Women's Health Initiative
Clinical Trial and Observational Study

Semi-Annual Progress Report
September 1, 2003 to February 29, 2004

Prepared by
WHI Clinical Coordinating Center
Fred Hutchinson Cancer Research Center

Ross Prentice, Principal Investigator

Funded by National Institutes of Health Contract No. N01-WH-2-2110

May 20, 2004

WHI Semi-Annual Progress Report

Contents Page

Executive Summary

This report, summarizing data accumulated through February 29, 2004 presents the current status of the three clinical trial components and the Observational Study of the Women's Health Initiative (WHI). The focus of this report is adherence to the interventions, completeness of follow-up, safety and event rate comparisons for each clinical trial component.

Both trials of the Hormone Replacement Therapy (HRT) component have been terminated and the initial results have been published. The current report shows intermediate endpoints and final adherence results for the Estrogen alone trial (ERT), clinical events rates by age, race/ethnicity, and hysterectomy status.

For the Dietary Modification (DM) component, 48,835 women were randomized. Intervention adherence is monitored by the difference between the Intervention and Control arms in Food Frequency Questionnaire (FFQ) percent energy from fat (C-I). Studywide, the FFQ mean difference between Intervention and Control women is 10.9% energy from fat at AV-1 decreasing to 7.9% at AV-8. The corresponding design assumptions for the C-I comparisons were 13% at year 1, diminishing by 0.25% per year. For fruit and vegetable intake, the mean difference between the arms remains consistently in excess of 1 more serving per day for Intervention vs. Control women. Similarly women in the Intervention arm consumed almost 1 more serving per day of grains at AV-1 than women in the Control arm, decreasing to one-third serving at AV-9. Currently, 3.9% of the DM participants are lost-to-follow-up or have stopped follow-up and 3.8% of participants are deceased. The average follow-up time for DM women is approximately 7.1 years. After adjustment for age, the current incidence rates of breast cancer, colorectal cancer, and CHD are approximately 115%, 70%, and 65%, respectively, of what was assumed in the study design. Cumulative event rates for all monitored outcomes are provided by age and race/ethnicity.

The Calcium and Vitamin D (CaD) component randomized 36,282 women previously recruited to the trial. Adherence to CaD supplements, defined as those women known to be consuming 80% or more of the prescribed dose, has remained steady since the last report at 53-64%. In the latest interval (Aug. 03- Feb. 04), the adherence summary remained stable for all annual visits. About 20-35% of women on study medication takes less than 80% of their CaD pills, but nonetheless, continue to be partially adherent. Follow-up rates for CaD participants are better than for the other CT components in part because of the delayed randomization into this trial component; only 2.2% of participants are lost-to-follow-up or have stopped follow-up, and 2.3% of the participants are known to be deceased. With an average of 6.0 years of follow-up, the current rates of hip fractures, colorectal cancer and invasive breast cancer in the placebo arm are approximately 45%, 75%, and 115% respectively, of what was assumed in the study design. As above, cumulative event rates are provided for all monitored outcomes by age and race/ethnicity.

Observational Study recruitment ended with 93,676 women enrolled. Follow-up rates suggest strong retention overall as response rates to mailings exceed 94% through year 8. Only 2.5% of OS participants have been lost or have stopped follow-up. Event rates by age, race/ethnicity and follow-up time (pre- vs. post-year 3 visit) are presented for all adjudicated outcomes.

Information on the timeliness and quality of outcomes ascertainment, clinical center performance is provided. Finally, a summary of all WHI publications and ancillary study activities is included.

1. Preliminary Remarks

This report documents study activities of the Women's Health Initiative (WHI) Clinical Trial (CT) and Observational Study (OS) through February 29, 2004. Topics include intervention adherence, follow-up, safety, intermediate and clinical outcomes, and specialized scientific efforts. Updates are provided for each study component separately with a section on outcomes devoted to data quality, processing and timeliness issues.

During the past 6 months, the major scientific activities of the WHI investigators have related to stopping the Estrogen Alone (ERT) trial and publishing the initial report from this study and publishing additional disease-specific results of the combined estrogen plus progestin (PERT) trial. Recent clinical trial publications include:

- Hsia J, Kotchen K, Bonds D, et al. Peripheral arterial disease in the randomized estrogen plus progestin trial Circulation. 2004;109(5):620-626.
- Chlebowski R, Wactawski-Wende J, Ritenbaugh C, et al. Estrogen Plus Progestin Influence on Colorectal Cancer Risk in Healthy Post-menopausal Women: Results from the Women's Health Initiative (WHI) Randomized Trial. NEJM 2004; 350. 991-1004.
- Women's Health Initiative Steering Committee. Effects of Conjugated Equine Estrogen in Postmenopausal Women with Hysterectomy: the Women's Health Initiative Randomized Trial. JAMA 2004:291:1701-1712
- The Women's Health Initiative Study Group; Dietary adherence in the women's health initiative dietary modification trial. J Am Diet Assoc. 2004;104(4):654-658.

In addition to these articles, a manuscript on the effect of PERT on diabetes has been accepted by Diabetologia and corresponding manuscripts on venous thromboembolisms, gynecologic symptoms, and urinary incontinence are nearing completion. A manuscript describing joint analysis of observational study and clinical trial data on combined hormones and cardiovascular disease (CHD, stroke, VT) has been submitted.

Analyses of additional biomarkers for CVD are progressing and some of these additional results should be ready for publication over the next few months. (Note results of some of the baseline analytes were published in the papers by Manson et al. (NEJM, 2003) on CHD and Smoller et al. (JAMA, 2003) on stroke.) Some additional work towards identifying biomarkers for other diseases is proceeding. The Case-Control Analyte Working Group, lead by Rebecca Jackson, has fostered several disease specific subgroups to propose analytes for subsequent measurement in appropriate case-control study designs for all clinical trial components. The CVD and Osteoporosis subgroups have submitted their proposals and the CVD proposal has already been approved. The breast cancer and colorectal cancer subgroups have not yet provided a formal proposal but each are encouraged to complete their task of the next few months. In addition, the potential for genome-wide scans and proteomics is being considered to further elucidate disease mechanisms.

In preparation for the reporting and interpretation of Dietary Modification Trial results a Nutritional Biomarker Study has been planned for implementation during May 2004 to March 2005. About 550 DM trial women (275 intervention, 275 control) drawn from 12 of the WHI clinical centers will participate. In collaboration with Dr. Dale Schoeller at the University of Wisconsin, energy consumption will be measured using a doubly labeled water technique, and protein consumption will be measured using urinary nitrogen. Blood concentrations will be assessed for various other nutrients. These objective measures will be used to calibrate food frequency estimates of energy consumption. The calibrated values are expected to play a fundamental role in the analysis and interpretation of DM trial data.

The NHLBI has recently informed the WHI investigators of their intent to support continued follow-up (without intervention) of all willing WHI participants through 2010. This will involve a streamlined version of the existing outcomes collection protocol, following the basic elements of the previously approved 2-year follow-up of women in the HRT program. Activities are underway to support the recruitment of women into this extended follow-up study.

Additional special efforts of the last few months included:

- Further development of close-out planning (Close-out Working Group, Rebecca Jackson, chair)
- Intensive performance monitoring and targeted support of Clinical Centers with regard to outcomes data processing to reduce backlogs and to assure rapid completion of the final trial database upon close-out.
- Initiation of the first competition among WHI investigators for access to DNA specimens from women in the CT.

All reports summarize Clinical Center (CC) data provided to the CCC by February 29, 2004. All data presented are derived from WHILMA, the study database. Data managed in WHILMA are those defined by standardized data collection procedures and instruments (see *WHI Manuals, Vol. 2 – Procedures* and *Vol. 3 – Forms*).

The WHI Clinical Coordinating Center (CCC) is located at Fred Hutchinson Cancer Research Center, in Seattle, WA. Several other groups contribute to the coordinating center effort through a contractual relationship with the CCC: University of Washington (Bruce Psaty, PI) for cardiovascular expertise; Wake Forest University (Sally Shumaker, PI) for clinical facilitation and behavioral expertise; Wake Forest University (Ron Prineas, PI) for centralized ECG reading; University of California, San Francisco (Steve Cummings, PI) for centralized bone densitometry reading and osteoporosis expertise; McKesson Bioservices (Frank Cammarata, PI) for drug distribution on specimen repository; Medical Research Laboratories (Evan Stein, PI), biospecimen analysis.

Clinical Center locations and Principal Investigators (PI) are listed in *Table 1.1*. We note that Denise Bonds is now the Principal Investigator for the Wake Forest Clinical Center and Gloria Sarto is the Principal Investigator of the Madison Wisconsin Clinical Center.

Table 1.1
WHI Clinical Centers and Principal Investigators

Institution	Principal Investigator	Location
Albert Einstein College of Medicine	Sylvia Smoller, PhD	Bronx, NY
Baylor College of Medicine	Jennifer Hays, PhD	Houston, TX
Brigham and Women's Hospital	Joann Manson, MD DrPH	Boston, MA
Emory University	Larry Phillips, MD	Atlanta, GA
Fred Hutchinson Cancer Research Center	Shirley Beresford, PhD	Seattle, WA
George Washington University	Judith Hsia, MD	Washington, DC
Kaiser Foundation Research Institute	Bette Caan, PhD	Oakland, CA
Kaiser Foundation Research Institute	Cheryl Ritenbaugh, PhD	Portland, OR
Medical College of Wisconsin	Jane Kotchen MD MPH	Milwaukee, WI
MedStar Research Institute	Barbara Howard, PhD	Washington, D.C.
Memorial Hospital of Rhode Island	Annlouise Assaf, PhD	Pawtucket, RI
Northwestern University	Linda Van Horn, PhD RD	Chicago and Evanston, IL
Ohio State University	Rebecca Jackson, MD	Columbus, OH
Research Foundation SUNY, Stony Brook	Dorothy Lane, MD MPH	Stony Brook, NY
Rush Presbyterian/St. Luke's Medical Ctr	Henry Black, MD	Chicago, IL
Stanford University	Marcia Stefanick, PhD	San Jose, CA
State University of New York, Buffalo	Jean Wactawski-Wende, PhD	Buffalo, NY
University of Alabama at Birmingham	Cora Lewis, MD MSP	Birmingham, AL
University of Arizona	Tamsen Bassford, MD	Tucson and Phoenix, AZ
University of California, Davis	John Robbins, MD	Sacramento, CA
University of California, Irvine	Allan Hubbell, MD	Irvine, CA
University of California, Los Angeles	Howard Judd, MD	Los Angeles, CA
University of California, Los Angeles	Rowan Chlebowski, MD PhD	Torrance, CA
University of California, San Diego	Robert Langer, MD MPH	La Jolla/Chula Vista, CA
University of Cincinnati	Margery Gass, MD	Cincinnati, OH

Table 1.1 (continued)
WHI Clinical Centers and Principal Investigators

Institution	Principal Investigator	Location
University of Florida	Marian Limacher, MD	Gainesville/ Jacksonville, FL
University of Hawaii	David Curb, MD	Honolulu, HI
University of Iowa	Robert Wallace, MD	Iowa City/Bettendorf, IA
University of Massachusetts	Judith Ockene, PhD	Worcester, MA
University of Medicine and Dentistry	Norman Lasser, MD PhD	Newark, NJ
University of Miami	Mary-Jo O'Sullivan, MD	Miami, FL
University of Minnesota	Karen Margolis, MD	Minneapolis, MN
University of Nevada	Robert Brunner, PhD	Reno, NV
University of North Carolina, Chapel Hill	Gerardo Heiss, MD MPH	Chapel Hill, NC
University of Pittsburgh	Lewis Kuller, MD DrPH	Pittsburgh, PA
University of Tennessee	Karen Johnson, MD	Memphis, TN
University of Texas	Robert Brzyski, MD	San Antonio, TX
University of Wisconsin	Gloria Sarto, MD	Madison, WI
Wake Forest University	Denise Bonds, MD	Winston-Salem/Greensboro, NC
Wayne State University	Susan Hendrix, DO	Detroit, MI

2. HRT Component

The intervention activities of the estrogen alone trial (ERT) were stopped in March 2004, following the decision of the NIH. The process of closing the trial generally followed the implementation plan used in closing the PERT trial, with the exception that the announcement of termination preceded the report of trial findings. ERT trial participants were informed by a letter from Dr. Barbara Alving, Acting Director of NHLBI, via a centralized mailing to be received on March 2. Clinical Centers initiated a separate contact, either by mail or phone, to begin collecting final outcomes for the intervention period, to collect any unused study medications and to unblind the study participants to their randomization assignment. The report from the trial was published in the April 14 issue of the Journal of the American Medical Association. After these results were published, clinical centers implemented a second mailing to provide study results and the information on the transition to a follow-up phase without intervention. All of the remaining elements of the WHI ERT protocol are continuing.

Participants in the other study arms are also being informed of ERT study findings and the continuing need for their participation is being reinforced. All participants are being made aware of the NHLBI decision to extend funding for follow-up (without intervention) through 2010.

2.1 Recruitment

Between 1993 and 1998, 27,347 women were randomized into the HRT component (99.4% of goal). Of these, 10,739 women had a prior hysterectomy (39%) and were randomized to ERT or placebo in equal proportions. The remaining 16,608 women with an intact uterus were randomized to PERT or its placebo, again in equal proportions for most of the recruitment period. *Table 2.1 – Hormone Replacement Therapy Component* documents the age and racial/ethnic distribution for each trial.

2.2 Adherence

Adherence to study medications is determined at clinic visits by weighing returned bottles, if available, or by self-report in the small proportion of women with missed pill collection. *Table 2.2 – HRT Adherence Summary for Participants Without a Uterus* provides final adherence data on all women who are considered due for each contact for participants with hysterectomy (ERT vs. placebo) trial. Almost all participants were randomized more than six years ago, 91% more than six years ago, 59% more than seven years ago and 1209 (11%) have been in the study more than nine years. In each of the follow-up years five through eight, an estimated 6% of participants stopped study pills. Corresponding adherence summaries for these years are 53%, 49%, 45%, and 44%. Reasons for stopping study medications are presented in *Tables 2.3* and *2.4*.

2.3 Symptoms

Women may report symptoms potentially related to HRT at routine follow-up contacts or through non-routine contacts with the CC. The primary symptoms being monitored are vaginal bleeding and breast changes. Reports of bleeding and breast changes by contact type and hysterectomy strata are shown in *Tables 2.5* and *2.6*, respectively. These displays combine data from the intervention and post-intervention period for PERT. Reports of bleeding in women on PERT reached a high of nearly 30% at 6 months (SAV-1), declining to approximately 7% after AV-5 with later reductions likely associated with the end of intervention. Reports of breast changes peaked at 6 weeks after randomization and declined to less than 2% in both strata, with a possible

further drop in the PERT arm after the intervention ended.

2.4 Intermediate Outcomes

Analyses of fasting blood samples, now with limited results available through AV-6 are presented by hysterectomy strata include levels of various micronutrients, clotting factors, and lipoproteins (*Table 2.7 – Blood Specimen Analysis: HRT Participant*). To examine possible racial/ethnic differences, parallel analyses within each racial/ethnic group are also provided (*Table 2.8*). Additional analyses of the case-control analytes are underway.

Bone mineral density (BMD) measures are collected in three clinical centers (Pittsburgh, Birmingham, and Tucson) at baseline and at follow-up years 1, 3, 6, and 9. Some data collected at Birmingham are not available because of a problem with the upgrade of the local machine. The available data, shown in *Table 2.9 – Bone Mineral Density Analysis: HRT Participants* suggest small but significant increases in BMD between baseline and AV-1, with larger differences observed over greater follow-up time (AV-3 and AV-6) for whole body and spine. For hip, the largest increase occurs at AV-3. Note however that data from the intervention and post-intervention period are again combined, affecting primarily the AV-9 and to a lesser extent the AV-6 results. *Table 2.10 – Bone Mineral Density Analysis: HRT Participants by Race/Ethnicity* presents BMD data for Black/African American, Hispanic/Latino, and White women participating in the HRT component at these three centers.

2.5 Vital Status

Table 2.11 – Lost-to-Follow-up and Vital Status presents data on the vital status and the participation status of participants in the HRT trial. A detailed description of CCC and clinic activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes Processing*. For operational purposes, we define CT participants to have an "unknown" participation status if there is no outcomes information from the participant for 18 months and no other contacts for 6 months. We note a difference in the rate of lost to follow-up between the women without a uterus (2.2%) and the women with a uterus (1.2%), presumably a result of the earlier closure of the PERT intervention. Currently, 4.4% of the HRT participants are lost-to-follow-up or have stopped follow-up, and 4.7% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or dead. Currently, the average follow-up for HRT participants is about 6.9 years, suggesting that approximately 19.0% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

2.6 Outcomes

Table 2.12 – Verified Outcomes (Annualized Percentages) contains counts of the number of verified, major WHI outcomes for HRT participants by age and race/ethnicity. We are reporting centrally adjudicated outcomes for those outcomes that are centrally adjudicated for all participants in a component and locally verified outcomes for events for which central adjudication has not yet been completed. Thus, for the HRT component we are using centrally adjudicated outcomes for clinical MI, DVT, PE, breast cancer, ovarian cancer, endometrial cancer, colorectal cancer, hip fractures, and death. The estimates of annualized incidence rates for many event types in several racial/ethnic subgroups should be viewed with caution as the small number of events observed to-date results in unstable estimates. Approximately 3% of the self-reported

outcomes have not yet been verified, so the numbers in this table can be seen as a lower bound of the actual number of outcomes that have occurred.

Compared to the design assumptions, we have observed about 75% of the expected number of CHD events, 90% of the expected number of breast cancers, 75% of the expected number of colorectal cancers, and about 45% of the expected number of hip fractures.

The central adjudicators have classified the strokes among HRT participants in one of six classes of the Glasgow scale, based on the condition of the participant at discharge:

1. Good recovery – participant can lead a full and independent life with or without minimal neurological deficit.

2. Moderately disabled – participant has neurological or intellectual impairment but is independent.

3. Severely disabled – participant conscious but totally dependent on others to get through daily activities.

4. Vegetative survival – participant has no obvious cortical functioning.

5. Dead. (All participants who died within one month of their stroke were classified in this category, irrespective of their actual cause of death.)

6. Unable to categorize based on available documentation.

The subclass *Non-disabling stroke* contains strokes with Glasgow scale classes 1 and 2; *Fatal/ disabling stroke* contains strokes with Glasgow scale classes 3 through 5; *Unknown status from stroke* contains strokes with Glasgow scale class 6 and strokes for which the Glasgow classification was not yet complete.

Table 2.13 – Verified Outcomes (Annualized Percentages) for HRT Participants Without and With Uterus compares the rates of the same verified outcomes according to baseline hysterectomy strata. For most cardiovascular outcomes the event rates are slightly larger for the women without a uterus, while for cancers of the female organs, the rates are slightly larger for women with a uterus. The differences in cardiovascular disease rates are consistent with the risk profile differences we have previously observed.

Table 2.14 – Frequency of Various Subcategories of Stroke Diagnosis presents the distribution of stroke diagnostic categories for HRT participants by hysterectomy status. The distribution of the subtype of stroke appears to be similar for the women with and without a uterus.

Table 2.15 – Frequency of Disability Levels Following Stroke compares the Glasgow scale for strokes between hysterectomy strata. From this table it appears that the largest number of strokes fall in Glasgow classes 1 and 2, the less disabling strokes, but a substantial number of participants die within one month of a stroke.

Table 2.16 – Counts (Annualized Percentages) of Participants with Self-Reported Outcomes contains counts of the number of self-reports by age and race/ethnicity for some outcomes that are

not verified in WHI. As most of the self-reported outcomes are somewhat over-reported (see *Section 6.3 – Outcomes Data Quality*), the numbers in this table should be taken as an upper bound on the number of events that have occurred in HRT participants.

2.7 Issues

With the closure now of both hormone therapy trials, the WHI investigators are devoting their efforts to data analysis and reporting and to planning for the extended follow-up period. Disease-specific reports of centrally adjudicated events occurring through February 29, 2004 are under development and will be finalized using the data available through August 31, 2004.

Table 2.1
Hormone Replacement Therapy Component Age – and Race/Ethnicity – Specific Recruitment

Data as of: February 29, 2004

HRT Participants	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age				
Overall	**27,347**			
50-54	3,421	125%	13%	10%
55-59	5,410	99%	20%	20%
60-69	12,364	100%	45%	45%
70-79	6,152	90%	22%	25%
Without Uterus	**10,739**			
50-54	1,396	113%	13%	10%
55-59	1,916	78%	18%	20%
60-69	4,852	88%	45%	45%
70-79	2,575	84%	24%	25%
With Uterus	**16,608**			
50-54	2,025	135%	12%	10%
55-59	3,494	116%	21%	20%
60-69	7,512	111%	45%	45%
70-79	3,577	95%	22%	25%
Race/Ethnicity				
Overall	**27,347**			
American Indian	130		<1%	
Asian	527		2%	
Black	2,738		10%	
Hispanic	1,537		6%	
White	22,030		81%	
Unknown	385		1%	
Without Uterus	**10,739**			
American Indian	75		1%	
Asian	164		2%	
Black	1,616		15%	
Hispanic	651		6%	
White	8,084		75%	
Unknown	149		1%	
With Uterus	**16,608**			
American Indian	55		<1%	
Asian	363		2%	
Black	1,122		7%	
Hispanic	886		5%	
White	13,946		84%	
Unknown	236		1%	

Table 2.2
HRT Adherence Summary for Participants Without a Uterus

Data as of: February 29, 2004

Contact	Due N	Conducted[1] N	%	Conducted in Window N	%	Stopped HRT during interval N	%	Missed Pill Collection N	%	Total with Collections N	%	Medication Rate[2,3] <50% N	%	Medication Rate[2,3] 50%-80% N	%	Medication Rate[2,3] 80% + N	%	Adherence Summary[4] %
Annual Visit – 1	10739	10352	96	8538	80	880	8	75	1	10625	99	826	8	1277	12	8522	80	80
Annual Visit – 2	10739	10061	94	7945	75	1041	10	184	2	9630	98	1015	10	1190	12	7425	76	70
Annual Visit – 3	10739	10045	94	7445	70	851	8	193	2	8574	98	896	10	1046	12	6632	76	63
Annual Visit – 4	10739	9839	92	6777	65	705	7	162	2	7758	98	688	9	953	12	6117	77	58
Annual Visit – 5	10739	9756	91	6363	61	671	6	122	2	7107	98	631	9	899	12	5577	77	53
Annual Visit – 6	9751	8763	90	5235	56	594	6	139	2	5843	98	490	8	737	12	4616	77	49
Annual Visit – 7	6322	5527	87	3118	52	382	6	99	3	3505	97	305	8	453	13	2747	76	45
Annual Visit – 8	3083	2682	87	1432	49	187	6	39	2	1628	98	154	9	182	11	1292	78	44
Annual Visit – 9	1209	1031	85	509	45	92	8	20	3	603	97	65	10	69	11	469	75	42

[1] Based on Form 33 collection.
[2] Medication rate calculated as number of pills taken divided by number of days since bottle(s) were dispensed.
[3] Percentage calculated based on denominator of total dispensation which is the sum of missed pill collection and total with collection.
[4] Adherence summary calculated as number of women consuming ≥ 80% of pills / # due for visit.
Note: Deceased women are excluded from all medication adherence calculations, but are included in the number "Due."

Table 2.3
Reasons for Stopping HRT[1]: HRT Participants Without Uterus

Data as of February 29, 2004

Reasons[2]	(N = 5773)	
Personal/family		
Demands of work	96	1.7%
Family illness, emergency or other family demands[3]	235	4.1%
Financial problems	11	0.2%
Lack of cooperation/support from family/friends[4]	69	1.2%
Living in nursing home	21	0.4%
Issues of interest in study[5]	150	2.6%
Travel		
Too far to CC	198	3.4%
Moved out of area or refuses to be followed to another CC	49	0.8%
Other travel issues[6]	112	1.9%
Visits & Procedures		
Doesn't like visits, calls	62	1.1%
Mammogram Issues[7]	41	0.7%
Doesn't like gynecologic procedures	14	0.2%
Doesn't like required forms or safety procedures[8]	99	1.7%
Problems with other procedures[9]	13	0.2%
Worried about health effects of medical tests/procedures	27	0.5%
Wants test results[10]	1	<0.1%
Problems with CC[11]	32	0.6%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Family illness, emergency or other family demands," "Death in the family or of a close friend," and "Caregiver responsibilities demanding time, effort, lifestyle changes."
[4] Combines "Lack of cooperation/support from family and/or friends" and "Family/friends request that she withdraw."
[5] Combines "Conflicting priorities other than work or family," "Feels discouraged regarding participation overall," "Loss of interest, boredom," "Feels it is not an important study," and "In another study in conflict with WHI intervention."
[6] Combines "Transportation problems (other than distance)," "Traffic," "Parking at CC," and "CC neighborhood/safety."
[7] Combines "Doesn't like mammograms (DM, HRT)" and "Cost of mammograms (DM, HRT)."
[8] Combines "Doesn't like filling out forms (other than those required for safety)," and "Doesn't like required safety forms and/or procedures (HRT, CaD)."
[9] Combines "Doesn't like having blood drawn," "Doesn't like ECG (DM, HRT)," and "Doesn't like other procedures (other than those required for safety)."
[10] Combines "Wants results of blood analyses," and "Wants results of bone mineral density measurement (BD sites only)."
[11] Combines "Problem with the CC," "Problem with CC staff person (other than DM Group Nutritionist)," and "Staff change/turnover."

Table 2.3 (continued)
Reasons for Stopping HRT[1]: HRT Participants Without Uterus

Data as of February 29, 2004

Reasons[2]	(N = 5773)	
Symptoms		
Vaginal bleeding	6	0.1%
Breast symptoms[3]	221	3.8%
Vaginal changes	15	0.3%
Hot flashes/night sweats	32	0.6%
Other[4]	1075	18.6%
Health Conditions		
Breast cancer	119	2.1%
Complex or atypical hyperplasia	0	0.0%
Endometrial cancer	2	<0.1%
Venous thromboembolism[5]	84	1.5%
High triglycerides (> 1000 mg/dL)	2	<0.1%
Malignant melanoma	21	0.4%
Gallbladder disease	21	0.4%
Heart attack	106	1.8%
Stroke	149	2.6%
Meningioma	6	0.1%
Depression	16	0.3%
Cholesterol (high or concern about levels)	12	0.2%
Osteoporosis	39	0.7%
Cognitive/memory changes	62	1.1%
Other[6]	683	11.8%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Breast tenderness (HRT)" and "Other breast changes (HRT)."
[4] Combines "Experiencing health problems or symptoms not due to intervention," "Reports other health problems or symptoms from the WHI intervention," "Reports health problems or symptoms from the WHI intervention," "Hair/skin changes," "Bloating/Gas," "Constipation," "Other gastrointestinal problems," "Headaches," "Weight loss/gain," "Low energy/too tired," "Possible allergic reaction," and "Other symptoms not listed above."
[5] Combines "Deep vein thrombosis," and "Pulmonary embolism."
[6] Combines "Removed from intervention due to WHI symptom management," "Removed from intervention due to adverse health event," "Communication problem," "Hypercalcemia," "Kidney failure/dialysis," "Renal calculi," "Arthritis," "Diabetes," "Loss of vision and/or hearing," and "Other health conditions not listed above."

Table 2.3 (continued)
Reasons for Stopping HRT[1]: HRT Participants Without Uterus

Data as of February 29, 2004

Reasons[2]	(N = 5773)	
Intervention		
Doesn't like randomized nature of intervention	99	1.7%
Expected some benefit from intervention	42	0.7%
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	4	0.1%
Takes too many pills	57	1.0%
Other pill issues[3]	169	2.9%
CaD Issues[4]	40	0.7%
DM Issues[5]	6	0.1%
Taking active HRT[6]	219	3.8%
Will not be on any HRT[7]	783	13.6%
Taking SERMs or other hormone medications[8]	51	0.9%
Other Health Issues		
Worried about cost if adverse effects occur	17	0.3%
Expected more health care	14	0.2%
Advised not to participate by health care provider[9]	664	11.5%
Study conflicts with other health issues[10]	611	10.6%
Other		
Other reasons not listed above	1174	20.3%
Refuses to give a reason	86	1.5%

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Doesn't like taking pills (HRT, CaD)," "Doesn't like taste of pills (HRT, CaD)," and "Unable to swallow pills (HRT, CaD)."
[4] Combines "Wants to take her own calcium (CaD)," "Feels diet is already sufficient in calcium/Vitamin D (CaD)," "Taking more than the maximum allowable IU of Vit D (CaD)," and "Taking Calcitriol (CaD)."
[5] Combines "Doesn't like DM requirements," "Problem with DM Group Nutritionist or group members (DM)," "Doesn't like DM eating pattern," "Doesn't like attending DM intervention classes (DM)," "Doesn't like self-monitoring (DM)," "Doesn't like budgeting fat grams (DM)," "Has concerns regarding long-term risks/benefits of low fat diet (DM)", "Unhappy that not losing weight (DM)", "Not in control of meal preparation (DM)", "Too difficult to meet or maintain dietary goals (DM)," "Doesn't like eating low fat diet (DM)," "Doesn't like eating 5 vegetables/fruits per day (DM)," "Doesn't like eating 6 grains per day (DM)," "Feels fat gram goal is unrealistic (DM)," and "Eating pattern conflicts with personal health beliefs (DM)."
[6] Combines "Has made a personal decision to go on active HRT (HRT)" and "Advised to go on active HRT by health care provider (HRT)."
[7] Combines "Has made a personal decision that she does not want to be on HRT (HRT)" and "Advised to not be on active HRT by health care provider (HRT)."
[8] Combines "Has made a personal decision to go on SERM (e.g., Evista/raloxifene, tamoxifen) (HRT)," "Advised to go on SERM (e.g., Evista/raloxifene, tamoxifen) by health care provider (HRT)," and "Taking testosterone medications (HRT)."
[9] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason."
[10] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues."

Table 2.4

Reasons for Stopping HRT[1] by Age at Screening and Race/Ethnicity: HRT Participants Without Uterus

Data as of February 29, 2004

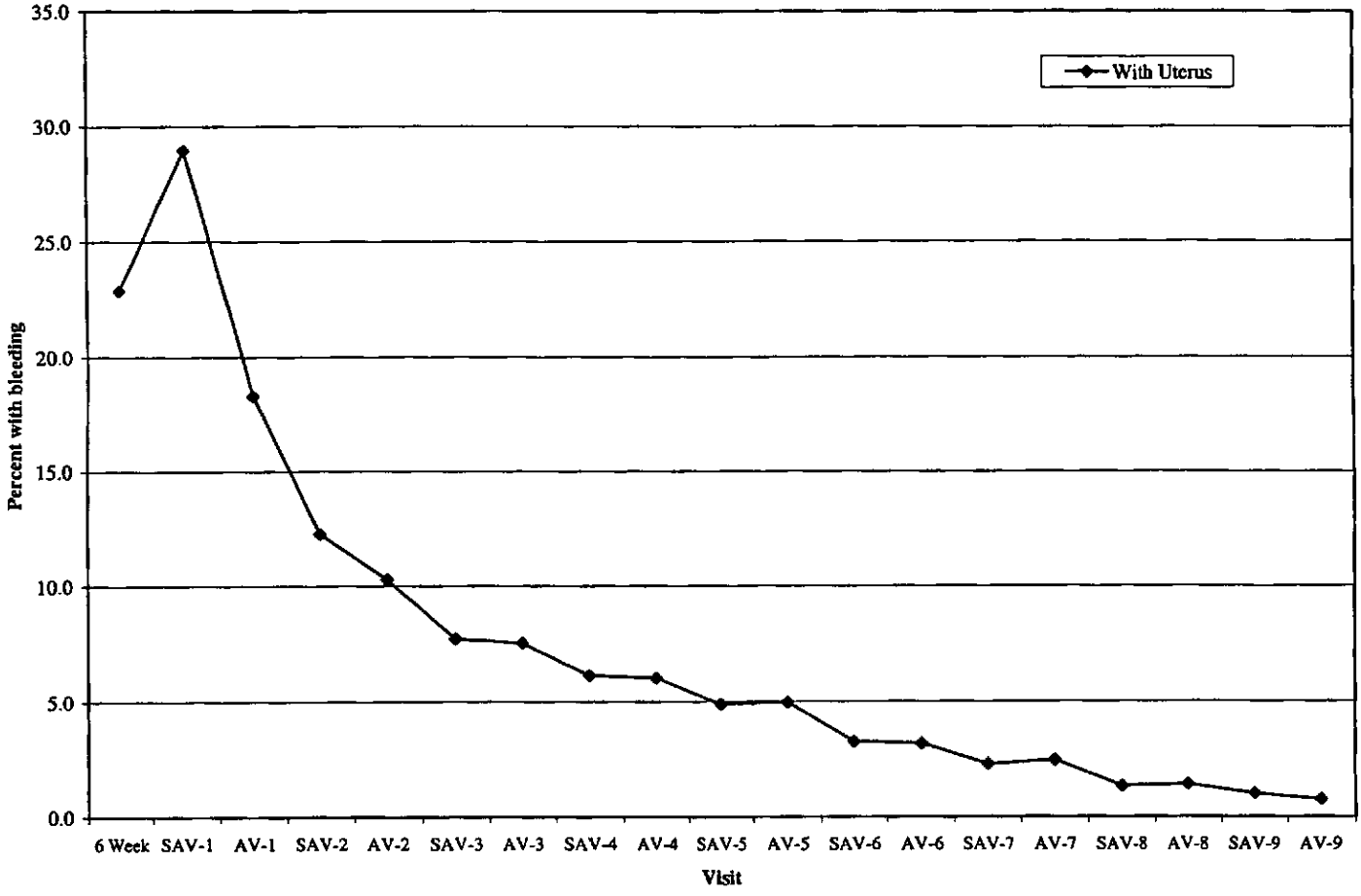
			Age at Screening							
	All (N = 10,739)		50 – 54 (N = 1,396)		55 – 59 (N = 1,916)		60 – 69 (N = 4,852)		70 –79 (N = 2,575)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping HRT	5773	53.8%	729	52.2%	978	51.0%	2518	51.9%	1548	60.1%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	235	4.1%	29	4.0%	47	4.8%	109	4.3%	50	3.2%
Vaginal bleeding	6	0.1%	1	0.1%	2	0.2%	2	0.1%	1	0.1%
Breast symptoms[6]	221	3.8%	17	2.3%	30	3.1%	89	3.5%	85	5.5%
Taking active HRT[7]	219	3.8%	35	4.8%	49	5.0%	90	3.6%	45	2.9%
Will not be on any HRT[8]	783	13.6%	70	9.6%	131	13.4%	359	14.3%	223	14.4%
Advised not to participate by health care provider[9]	664	11.5%	86	11.8%	108	11.0%	283	11.2%	187	12.1%
Study conflicts with other health issues[10]	611	10.6%	84	11.5%	101	10.3%	272	10.8%	154	9.9%

	Race/Ethnicity											
	American Indian/ Alaskan Native (N = 75)		Asian/Pacific Islander (N = 164)		Black/African American (N = 1,616)		Hispanic/Latino (N = 651)		White (N = 8,084)		Unknown (N = 149)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping HRT	43	57.3%	88	53.7%	898	55.6%	389	59.8%	4281	53.0%	74	49.7%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	1	2.3%	2	2.3%	50	5.6%	26	6.7%	153	3.6%	3	4.1%
Vaginal bleeding	0	0.0%	0	0.0%	2	0.2%	1	0.3%	3	0.1%	0	0.0%
Breast symptoms[6]	4	9.3%	2	2.3%	32	3.6%	15	3.9%	166	3.9%	2	2.7%
Taking active HRT[7]	1	2.3%	1	1.1%	24	2.7%	16	4.1%	174	4.1%	3	4.1%
Will not be on any HRT[8]	6	14.0%	13	14.8%	110	12.2%	40	10.3%	603	14.1%	11	14.9%
Advised not to participate by health care provider[9]	6	14.0%	10	11.4%	72	8.0%	43	11.1%	523	12.2%	10	13.5%
Study conflicts with other health issues[10]	5	11.6%	12	13.6%	71	7.9%	30	7.7%	485	11.3%	8	10.8%

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Percentages are of HRT participants without uterus in the same age or race/ethnicity category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of HRT participants without uterus in the same age or race/ethnicity category who stopped HRT.
[5] Combines "Family illness, emergency or other family demands," "Death in the family or of a close friend," and "Caregiver responsibilities demanding time, effort, lifestyle changes."
[6] Combines "Breast tenderness (HRT)" and "Other breast changes (HRT)."
[7] Combines "Has made a personal decision to go on active HRT (HRT)" and "Advised to go on active HRT by health care provider (HRT)."
[8] Combines "Has made a personal decision that she does not want to be on HRT (HRT)" and "Advised to not be on active HRT by health care provider (HRT)."
[9] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason."
[10] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues."

Table 2.5
Reports of Bleeding

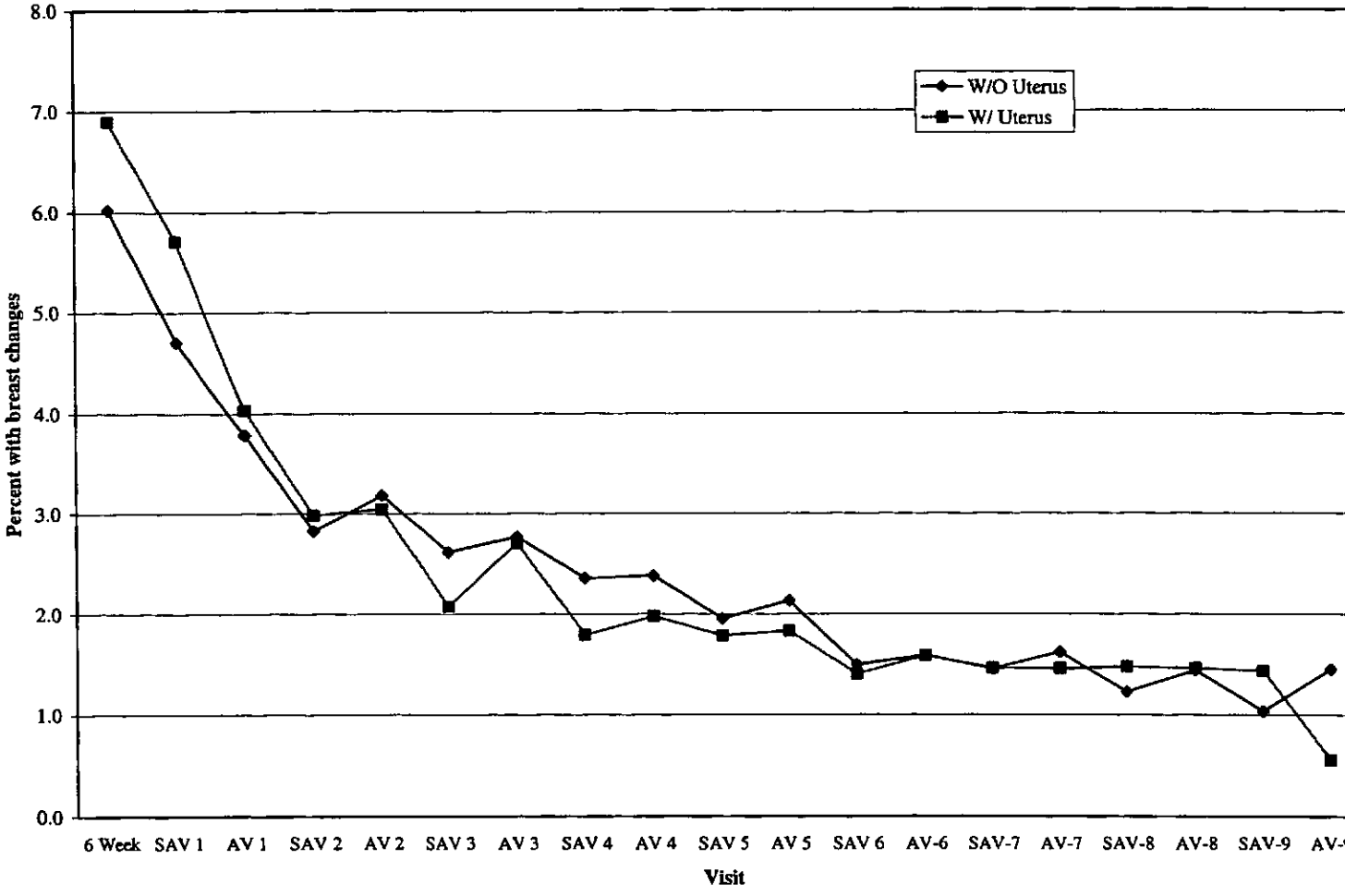
Data as of: February 29, 2004



Contact	With Uterus	
Semi-Annual Visit 3 – Number with Bleeding	1196	(7.7%)
Annual Visit 3 – Number with Bleeding	1186	(7.5%)
Semi-Annual Visit 4 – Number with Bleeding	950	(6.1%)
Annual Visit 4 – Number with Bleeding	937	(6.0%)
Semi-Annual Visit 5 – Number with Bleeding	753	(4.9%)
Annual Visit 5 – Number with Bleeding	766	(5.0%)
Semi-Annual Visit 6 – Number with Bleeding	494	(3.3%)
Annual Visit 6 – Number with Bleeding	440	(3.2%)
Semi-Annual Visit 7 – Number with Bleeding	261	(2.3%)
Annual Visit 7 – Number with Bleeding	214	(2.5%)
Semi-Annual Visit 8 – Number with Bleeding	81	(1.3%)
Annual Visit 8 – Number with Bleeding	58	(1.4%)
Semi-Annual Visit 9 – Number with Bleeding	25	(1.0%)
Annual Visit 9 – Number with Bleeding	11	(0.7%)

Table 2.6
Reports of Breast Changes

Data as of: February 29, 2004



Contact	Without Uterus		With Uterus	
Semi-Annual Visit 3 – Number with Breast Changes	220	(2.6%)	276	(2.1%)
Annual Visit 3 – Number with Breast Changes	229	(2.8%)	356	(2.7%)
Semi-Annual Visit 4 – Number with Breast Changes	183	(2.4%)	223	(1.8%)
Annual Visit 4 – Number with Breast Changes	179	(2.4%)	243	(2.0%)
Semi-Annual Visit 5 – Number with Breast Changes	141	(2.0%)	208	(1.8%)
Annual Visit 5 – Number with Breast Changes	150	(2.1%)	208	(1.8%)
Semi-Annual Visit 6 – Number with Breast Changes	99	(1.5%)	143	(1.4%)
Annual Visit 6 – Number with Breast Changes	94	(1.6%)	135	(1.6%)
Semi-Annual Visit 7 – Number with Breast Changes	71	(1.5%)	93	(1.5%)
Annual Visit 7 – Number with Breast Changes	58	(1.6%)	66	(1.5%)
Semi-Annual Visit 8 – Number with Breast Changes	31	(1.2%)	43	(1.5%)
Annual Visit 8 – Number with Breast Changes	24	(1.4%)	28	(1.5%)
Semi-Annual Visit 9 – Number with Breast Changes	11	(1.0%)	16	(1.4%)
Annual Visit 9 – Number with Breast Changes	9	(1.4%)	3	(0.6%)

Table 2.7
Blood Specimen Analysis: HRT Participants

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	1163	0.07	0.07	1468	0.09	0.08
AV-1	1022	0.07	0.06	1365	0.08	0.08
AV-3	884	0.06	0.06	1206	0.07	0.08
AV-6	266	0.05	0.05	359	0.08	0.07
AV-1 – Baseline	1000	-0.01	0.06	1332	-0.01	0.06
AV-3 – Baseline	868	-0.01	0.06	1177	-0.01	0.07
AV-6 – Baseline	261	-0.02	0.08	346	-0.01	0.06
Beta-Carotene (µg/ml)						
Baseline	1162	0.29	0.27	1468	0.34	0.33
AV-1	1021	0.26	0.25	1366	0.31	0.30
AV-3	884	0.25	0.25	1206	0.32	0.38
AV-6	266	0.26	0.28	359	0.32	0.33
AV-1 – Baseline	999	-0.03	0.22	1333	-0.04	0.21
AV-3 – Baseline	867	-0.04	0.25	1177	-0.03	0.31
AV-6 – Baseline	261	-0.03	0.24	346	-0.02	0.31
Alpha-tocopherol (µg/ml)						
Baseline	1163	16.09	7.04	1468	16.31	7.70
AV-1	1022	17.70	8.91	1366	16.82	7.42
AV-3	884	17.83	8.30	1206	18.26	8.17
AV-6	266	18.88	8.90	359	18.67	8.61
AV-1 – Baseline	1000	1.63	6.25	1333	0.51	5.73
AV-3 – Baseline	868	1.76	6.80	1177	2.00	7.28
AV-6 – Baseline	261	3.60	8.67	346	3.39	7.88
Gamma-tocopherol (µg/ml)						
Baseline	1163	2.48	1.65	1468	2.24	1.40
AV-1	1022	2.22	1.84	1366	1.84	1.24
AV-3	884	2.00	1.49	1206	1.66	1.24
AV-6	266	1.83	1.43	359	1.71	1.41
AV-1 – Baseline	1000	-0.30	1.13	1333	-0.37	0.93
AV-3 – Baseline	868	-0.54	1.19	1177	-0.57	1.17
AV-6 – Baseline	261	-0.64	1.63	346	-0.64	1.33
Beta-Cryptoxanthine (µg/ml)						
Baseline	1163	0.08	0.08	1468	0.09	0.10
AV-1	1022	0.08	0.07	1365	0.09	0.09
AV-3	884	0.08	0.07	1206	0.10	0.09
AV-6	266	0.10	0.18	359	0.10	0.09
AV-1 – Baseline	1000	-0.00	0.06	1332	-0.01	0.07
AV-3 – Baseline	868	-0.00	0.07	1177	0.00	0.09
AV-6 – Baseline	261	0.02	0.17	346	0.02	0.09

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 2.7 (continued)
Blood Specimen Analysis: HRT Participants

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Lycopene (μg/ml)						
Baseline	1163	0.40	0.20	1468	0.41	0.20
AV-1	1022	0.39	0.19	1366	0.40	0.19
AV-3	884	0.35	0.18	1206	0.38	0.21
AV-6	266	0.36	0.20	359	0.36	0.19
AV-1 – Baseline	1000	-0.01	0.17	1333	-0.01	0.17
AV-3 – Baseline	868	-0.05	0.20	1177	-0.03	0.21
AV-6 – Baseline	261	-0.01	0.22	346	-0.05	0.22
Lutein and Zeaxanthin (μg/ml)						
Baseline	1163	0.20	0.10	1468	0.21	0.09
AV-1	1022	0.20	0.10	1366	0.21	0.10
AV-3	884	0.19	0.10	1206	0.20	0.09
AV-6	266	0.17	0.12	359	0.18	0.09
AV-1 – Baseline	1000	0.00	0.07	1333	0.00	0.07
AV-3 – Baseline	868	-0.01	0.07	1177	-0.02	0.08
AV-6 – Baseline	261	-0.03	0.10	346	-0.03	0.09
Retinol (μg/ml)						
Baseline	1163	0.60	0.15	1468	0.60	0.15
AV-1	1022	0.63	0.16	1366	0.61	0.15
AV-3	884	0.62	0.16	1206	0.61	0.16
AV-6	266	0.65	0.17	359	0.63	0.16
AV-1 – Baseline	1000	0.03	0.11	1333	0.01	0.10
AV-3 – Baseline	868	0.02	0.13	1177	0.00	0.13
AV-6 – Baseline	261	0.06	0.15	346	0.05	0.13
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	1121	128.49	28.82	1415	123.49	28.32
AV-1	973	139.42	35.19	1319	129.63	31.01
AV-3	848	135.80	33.71	1148	128.21	31.65
AV-6	266	127.66	30.76	343	115.68	27.39
AV-1 – Baseline	927	10.40	25.42	1248	5.94	22.52
AV-3 – Baseline	807	8.02	30.71	1084	4.92	28.04
AV-6 – Baseline	254	2.63	28.54	326	-3.79	24.28
Factor VII C (%)[2]						
Baseline	1101	129.99	28.24	1396	125.15	27.13
AV-1	961	136.32	31.68	1308	124.89	27.96
AV-3	844	135.30	34.41	1141	127.15	32.21
AV-6	265	147.99	39.12	344	131.82	32.46
AV-1 – Baseline	899	6.23	23.93	1220	-0.58	21.84
AV-3 – Baseline	787	7.42	29.14	1062	2.12	27.50
AV-6 – Baseline	246	17.82	33.04	320	6.65	28.32
Fibrinogen (mg/dl)						
Baseline	1118	312.18	63.50	1413	306.41	59.37
AV-1	971	301.34	61.46	1316	299.11	59.45
AV-3	848	294.21	59.18	1146	290.92	57.51
AV-6	266	287.72	55.17	345	291.74	56.89
AV-1 – Baseline	923	-11.50	52.68	1243	-7.95	53.17
AV-3 – Baseline	804	-17.88	61.65	1080	-15.41	56.61
AV-6 – Baseline	253	-23.49	59.32	327	-12.33	54.98

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.
[2] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.7 (continued)
Blood Specimen Analysis: HRT Participants

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Hormones / Other						
Glucose (mg/dl)						
Baseline	1160	105.16	35.35	1466	100.47	26.73
AV-1	1020	102.91	31.69	1362	98.72	24.60
AV-3	903	101.96	31.58	1222	98.65	26.39
AV-6	270	103.19	27.15	361	99.51	26.76
AV-1 – Baseline	995	-2.76	21.30	1326	-1.94	17.24
AV-3 – Baseline	885	-3.60	26.12	1192	-2.50	20.45
AV-6 – Baseline	265	0.07	21.29	346	-0.70	18.93
Insulin (μIU/ml)						
Baseline	1139	12.88	10.62	1421	11.42	6.86
AV-1	1004	12.16	8.14	1317	11.38	7.18
AV-3	853	13.60	11.32	1155	12.40	7.29
AV-6	270	11.89	20.23	360	11.30	21.12
AV-1 – Baseline	964	-0.74	5.98	1264	-0.09	5.56
AV-3 – Baseline	822	0.58	9.12	1092	1.06	6.61
AV-6 – Baseline	263	-1.41	8.98	342	0.67	18.40
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	1163	162.97	99.73	1469	146.01	74.89
AV-1	1020	176.31	132.80	1365	149.30	75.05
AV-3	902	169.67	82.73	1220	152.49	81.18
AV-6	270	173.66	76.77	359	151.60	67.99
AV-1 – Baseline	997	13.67	73.57	1332	3.11	55.64
AV-3 – Baseline	883	7.35	81.70	1191	6.51	64.92
AV-6 – Baseline	264	2.69	134.41	346	8.58	62.97
Total Cholesterol (mg/dl)						
Baseline	1163	229.63	41.21	1469	224.84	36.85
AV-1	1020	223.25	40.59	1365	215.84	35.22
AV-3	902	218.71	36.84	1220	215.04	35.21
AV-6	270	212.39	39.29	359	215.05	35.23
AV-1 – Baseline	997	-6.04	29.85	1332	-8.79	28.18
AV-3 – Baseline	883	-10.82	34.49	1191	-8.65	31.79
AV-6 – Baseline	264	-17.41	42.34	346	-9.94	37.29
LDL-C (mg/dl)						
Baseline	1139	142.06	36.82	1444	138.73	32.93
AV-1	998	128.48	35.85	1340	127.13	32.49
AV-3	881	126.90	34.80	1196	127.03	33.00
AV-6	266	120.74	36.56	356	126.44	32.80
AV-1 – Baseline	966	-13.26	27.27	1298	-11.34	25.66
AV-3 – Baseline	853	-15.50	32.02	1153	-10.60	29.43
AV-6 – Baseline	254	-21.67	39.57	339	-11.83	36.09
HDL-C (mg/dl)						
Baseline	1157	55.59	14.52	1464	56.92	14.38
AV-1	1018	59.92	16.83	1365	59.12	14.89
AV-3	895	58.65	16.57	1217	58.20	15.20
AV-6	270	57.68	14.97	359	58.25	14.20
AV-1 – Baseline	993	4.11	9.36	1327	2.28	8.15
AV-3 – Baseline	873	2.97	10.28	1184	1.32	9.46
AV-6 – Baseline	262	2.14	12.11	346	-0.08	9.75

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 2.7 (continued)
Blood Specimen Analysis: HRT Participants

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
HDL-2 (mg/dl)						
Baseline	1133	16.92	7.52	1423	17.72	7.57
AV-1	995	19.35	8.80	1332	19.05	8.12
AV-3	882	16.51	6.82	1197	16.29	6.38
AV-6	268	16.26	6.24	358	16.48	6.08
AV-1 – Baseline	952	2.05	5.05	1263	1.19	4.67
AV-3 – Baseline	845	-0.60	5.55	1133	-1.54	5.37
AV-6 – Baseline	257	0.53	6.73	332	-1.05	6.63
HDL-3 (mg/dl)						
Baseline	1134	38.75	8.41	1423	39.14	8.11
AV-1	997	40.86	9.49	1333	40.10	8.18
AV-3	882	42.05	10.63	1197	41.80	9.45
AV-6	268	41.47	10.13	358	41.78	9.20
AV-1 – Baseline	954	2.10	5.77	1264	1.02	5.20
AV-3 – Baseline	846	3.57	7.31	1133	2.74	6.64
AV-6 – Baseline	258	1.58	8.35	332	0.93	6.93
Lp(a) (mg/dl)						
Baseline	1141	26.81	26.19	1449	27.34	27.77
AV-1	1005	25.40	27.00	1351	25.26	27.27
AV-3	872	22.09	21.88	1182	22.71	23.33
AV-6	269	30.07	22.58	358	31.39	24.02
AV-1 – Baseline	970	-1.12	10.84	1303	-2.00	10.88
AV-3 – Baseline	841	-4.42	15.18	1140	-4.31	15.12
AV-6 – Baseline	259	5.46	17.93	339	6.88	15.39

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 2.8
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (μg/ml)						
Baseline	32	0.06	0.04	30	0.05	0.04
AV-1	27	0.07	0.08	25	0.05	0.03
AV-3	22	0.05	0.05	23	0.05	0.03
AV-6	2	0.01	0.00	2	0.09	0.00
AV-1 - Baseline	27	0.01	0.06	24	-0.01	0.03
AV-3 - Baseline	22	-0.01	0.04	22	-0.01	0.04
AV-6 – Baseline	2	-0.01	0.01	2	0.01	0.08
Beta-Carotene (μg/ml)						
Baseline	32	0.33	0.38	30	0.25	0.20
AV-1	27	0.34	0.39	25	0.30	0.32
AV-3	22	0.32	0.29	23	0.25	0.29
AV-6	2	0.02	0.00	2	0.25	0.06
AV-1 - Baseline	27	-0.02	0.24	24	0.03	0.17
AV-3 - Baseline	22	-0.08	0.27	22	0.01	0.20
AV-6 – Baseline	2	-0.03	0.02	2	0.03	0.15
Alpha-tocopherol (μg/ml)						
Baseline	32	18.70	9.89	30	13.04	4.96
AV-1	27	19.18	10.00	25	14.86	8.17
AV-3	22	18.99	6.99	23	13.00	4.00
AV-6	2	25.84	28.77	2	12.04	0.27
AV-1 - Baseline	27	1.33	6.21	24	2.08	8.17
AV-3 - Baseline	22	0.65	7.44	22	0.19	3.22
AV-6 – Baseline	2	11.07	30.34	2	1.94	1.10
Gamma-tocopherol (μg/ml)						
Baseline	32	2.47	1.64	30	3.06	1.80
AV-1	27	2.64	2.73	25	2.34	0.99
AV-3	22	2.10	1.67	23	2.16	0.80
AV-6	2	2.74	3.03	2	2.65	0.28
AV-1 - Baseline	27	0.04	1.81	24	-0.76	1.95
AV-3 - Baseline	22	-0.49	1.20	22	-0.51	1.06
AV-6 – Baseline	2	-2.29	0.74	2	0.20	0.47
Beta-Cryptoxanthine (μg/ml)						
Baseline	32	0.09	0.11	30	0.06	0.03
AV-1	27	0.08	0.06	25	0.07	0.05
AV-3	22	0.10	0.07	23	0.08	0.06
AV-6	2	0.03	0.02	2	0.22	0.10
AV-1 - Baseline	27	-0.01	0.10	24	0.01	0.04
AV-3 - Baseline	22	-0.00	0.11	22	0.02	0.06
AV-6 – Baseline	2	-0.02	0.06	2	0.13	0.09
Lycopene (μg/ml)						
Baseline	32	0.37	0.22	30	0.39	0.16
AV-1	27	0.40	0.21	25	0.42	0.18
AV-3	22	0.37	0.20	23	0.33	0.16
AV-6	2	0.26	0.06	2	0.45	0.21
AV-1 - Baseline	27	0.03	0.21	24	0.05	0.16
AV-3 - Baseline	22	-0.03	0.22	22	-0.03	0.19
AV-6 – Baseline	2	-0.05	0.08	2	0.14	0.04

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lutein and Zeaxanthin (µg/ml)						
Baseline	32	0.21	0.10	30	0.18	0.09
AV-1	27	0.25	0.15	25	0.18	0.09
AV-3	22	0.22	0.15	23	0.18	0.08
AV-6	2	0.09	0.01	2	0.24	0.04
AV-1 - Baseline	27	0.03	0.09	24	-0.00	0.05
AV-3 - Baseline	22	-0.00	0.11	22	-0.01	0.05
AV-6 - Baseline	2	-0.05	0.06	2	-0.04	0.21
Retinol (µg/ml)						
Baseline	32	0.62	0.20	30	0.52	0.12
AV-1	27	0.65	0.19	25	0.55	0.16
AV-3	22	0.66	0.20	23	0.57	0.15
AV-6	2	0.92	0.05	2	0.50	0.02
AV-1 - Baseline	27	0.05	0.07	24	0.03	0.09
AV-3 - Baseline	22	0.03	0.14	22	0.04	0.12
AV-6 – Baseline	2	0.22	0.16	2	0.09	0.02
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	30	144.43	37.09	27	118.30	32.15
AV-1	26	154.77	44.02	25	126.84	35.71
AV-3	21	146.14	44.81	24	122.75	30.44
AV-6	2	154.50	12.02	2	111.00	5.66
AV-1 – Baseline	24	13.08	28.42	21	1.95	20.69
AV-3 – Baseline	20	4.45	34.53	21	3.10	23.59
AV-6 – Baseline	2	3.50	16.26	2	-16.00	25.46
Factor VII C (%)[1]						
Baseline	30	141.67	30.83	27	117.67	33.09
AV-1	25	141.24	30.15	25	126.44	32.24
AV-3	21	146.29	41.33	24	124.38	42.77
AV-6	2	191.00	11.31	2	137.00	11.31
AV-1 – Baseline	23	6.70	16.45	21	3.90	23.09
AV-3 – Baseline	20	10.65	33.02	21	6.90	34.93
AV-6 – Baseline	2	46.50	2.12	2	23.00	2.83
Fibrinogen (mg/dl)						
Baseline	30	325.93	67.56	27	312.41	79.21
AV-1	26	315.69	83.44	25	307.40	76.47
AV-3	21	320.38	61.64	24	283.08	58.72
AV-6	2	293.00	9.90	2	279.50	9.19
AV-1 – Baseline	24	-9.04	75.45	21	-13.33	52.01
AV-3 – Baseline	20	-9.75	66.27	21	-34.71	57.48
AV-6 – Baseline	2	-11.50	62.93	2	-32.00	33.94

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.8 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Hormones / Other						
Glucose (mg/dl)						
Baseline	32	112.22	42.33	30	116.17	51.66
AV-1	27	112.30	42.55	25	113.44	60.34
AV-3	23	104.65	35.88	25	109.80	52.89
AV-6	2	172.50	40.31	2	113.50	12.02
AV-1 – Baseline	27	-3.59	41.95	24	0.67	28.55
AV-3 – Baseline	23	-6.17	44.57	24	-2.50	31.91
AV-6 – Baseline	2	36.50	62.93	2	5.00	7.07
Insulin (μIU/ml)						
Baseline	32	13.63	8.05	30	12.61	8.81
AV-1	27	13.22	7.68	24	12.52	7.35
AV-3	21	12.42	5.81	22	11.63	6.05
AV-6	2	23.50	5.94	2	15.90	16.12
AV-1 – Baseline	27	-0.86	3.72	23	-0.26	2.88
AV-3 – Baseline	21	-0.29	6.77	21	0.04	5.82
AV-6 – Baseline	2	-1.65	9.83	2	-2.65	5.73
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	31	186.87	107.13	30	154.20	84.64
AV-1	27	214.63	159.36	25	161.12	100.16
AV-3	23	207.04	128.12	25	158.68	83.16
AV-6	2	307.00	18.38	2	141.50	34.65
AV-1 – Baseline	26	35.85	98.82	24	10.88	56.74
AV-3 – Baseline	22	26.18	71.10	24	7.04	43.56
AV-6 – Baseline	1	N/A	N/A	2	22.50	40.31
Total Cholesterol (mg/dl)						
Baseline	31	239.94	46.31	30	218.70	42.32
AV-1	27	230.78	47.19	25	208.32	41.70
AV-3	23	228.39	39.50	25	211.20	42.96
AV-6	2	173.00	15.56	2	178.50	17.68
AV-1 – Baseline	26	-4.23	27.84	24	-2.83	19.24
AV-3 – Baseline	22	-8.23	39.34	24	-0.96	25.44
AV-6 – Baseline	1	N/A	N/A	2	-0.50	10.61
LDL-C (mg/dl)						
Baseline	28	143.11	28.19	30	133.93	38.98
AV-1	23	125.13	38.01	24	122.21	39.54
AV-3	20	134.60	37.28	25	123.88	41.47
AV-6	2	69.50	21.92	2	88.00	1.41
AV-1 – Baseline	22	-15.77	25.61	23	-7.04	20.73
AV-3 – Baseline	20	-12.05	30.82	24	-3.25	25.32
AV-6 – Baseline	1	N/A	N/A	2	-5.00	21.21
HDL-C (mg/dl)						
Baseline	31	54.71	13.06	30	53.90	14.50
AV-1	27	59.44	15.82	25	56.28	13.48
AV-3	23	59.04	17.07	25	55.64	13.81
AV-6	2	42.00	2.83	2	62.50	26.16
AV-1 – Baseline	26	5.04	7.68	24	2.67	7.85
AV-3 – Baseline	22	4.55	8.88	24	1.00	7.68
AV-6 – Baseline	1	-6.00	N/A	2	0.00	2.83

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
HDL-2 (mg/dl)						
Baseline	31	16.55	5.86	30	16.27	6.51
AV-1	26	19.42	7.17	25	16.76	5.80
AV-3	22	17.27	6.47	25	15.04	5.79
AV-6	2	8.50	0.71	2	16.50	9.19
AV-1 – Baseline	25	2.68	3.67	24	0.50	4.31
AV-3 – Baseline	21	0.10	4.18	24	-1.63	3.56
AV-6 – Baseline	1	N/A	N/A	2	-4.50	0.71
HDL-3 (mg/dl)						
Baseline	32	38.06	7.75	30	37.63	8.72
AV-1	26	40.69	9.38	25	39.52	9.30
AV-3	22	41.91	11.73	25	40.60	8.96
AV-6	2	33.50	3.54	2	46.00	16.97
AV-1 – Baseline	26	2.69	4.87	24	2.17	4.50
AV-3 – Baseline	22	3.68	6.52	24	2.63	6.00
AV-6 – Baseline	2	-0.50	2.12	2	4.50	3.54
Lp(a) (mg/dl)						
Baseline	31	35.90	39.11	30	21.83	32.28
AV-1	26	32.08	43.78	25	14.32	15.48
AV-3	22	25.91	27.25	23	18.87	26.63
AV-6	2	17.50	10.61	2	16.00	12.73
AV-1 – Baseline	26	-0.50	14.62	24	-2.00	5.50
AV-3 – Baseline	21	-8.62	23.29	22	-5.59	12.85
AV-6 – Baseline	2	12.00	4.24	2	4.00	2.83

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: Asian/Pacific Islander

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	50	0.12	0.10	124	0.12	0.07
AV-1	45	0.09	0.07	115	0.11	0.08
AV-3	43	0.08	0.07	101	0.09	0.06
AV-6	8	0.10	0.08	20	0.10	0.09
AV-1 - Baseline	45	-0.04	0.09	113	-0.01	0.07
AV-3 - Baseline	43	-0.05	0.10	99	-0.03	0.07
AV-6 – Baseline	8	-0.04	0.11	19	-0.00	0.08
Beta-Carotene (µg/ml)						
Baseline	50	0.57	0.53	124	0.54	0.37
AV-1	45	0.40	0.33	115	0.44	0.27
AV-3	43	0.40	0.36	101	0.45	0.36
AV-6	8	0.52	0.33	20	0.47	0.36
AV-1 - Baseline	45	-0.13	0.30	113	-0.10	0.30
AV-3 - Baseline	43	-0.15	0.34	99	-0.10	0.37
AV-6 – Baseline	8	-0.05	0.21	19	0.11	0.29
Alpha-tocopherol (µg/ml)						
Baseline	50	20.49	8.12	124	18.62	8.88
AV-1	45	21.30	8.68	115	19.55	10.14
AV-3	43	22.91	9.91	101	21.64	13.46
AV-6	8	27.13	17.84	20	22.05	8.83
AV-1 - Baseline	45	0.90	5.79	113	0.69	6.09
AV-3 - Baseline	43	1.94	7.44	99	3.01	10.64
AV-6 – Baseline	8	6.08	13.20	19	7.36	7.98
Gamma-tocopherol (µg/ml)						
Baseline	50	1.67	1.24	124	1.55	1.06
AV-1	45	1.36	1.15	115	1.26	0.99
AV-3	43	1.22	1.06	101	1.20	0.93
AV-6	8	1.25	1.18	20	1.14	0.82
AV-1 - Baseline	45	-0.27	0.71	113	-0.26	0.76
AV-3 - Baseline	43	-0.37	0.98	99	-0.40	0.97
AV-6 – Baseline	8	-0.21	0.91	19	-0.71	1.15
Beta-Cryptoxanthine (µg/ml)						
Baseline	50	0.16	0.14	124	0.24	0.37
AV-1	45	0.17	0.19	115	0.23	0.34
AV-3	43	0.19	0.24	101	0.23	0.24
AV-6	8	0.67	0.95	20	0.25	0.25
AV-1 - Baseline	45	0.01	0.14	113	-0.02	0.25
AV-3 - Baseline	43	0.02	0.21	99	-0.02	0.29
AV-6 – Baseline	8	0.52	0.91	19	0.09	0.23
Lycopene (µg/ml)						
Baseline	50	0.42	0.25	124	0.40	0.21
AV-1	45	0.35	0.19	115	0.36	0.19
AV-3	43	0.30	0.20	101	0.33	0.18
AV-6	8	0.34	0.20	20	0.38	0.21
AV-1 - Baseline	45	-0.06	0.19	113	-0.04	0.19
AV-3 - Baseline	43	-0.10	0.17	99	-0.07	0.21
AV-6 – Baseline	8	0.01	0.22	19	-0.07	0.24

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lutein and Zeaxanthin (μg/ml)						
Baseline	50	0.30	0.14	124	0.29	0.11
AV-1	45	0.28	0.13	115	0.28	0.12
AV-3	43	0.25	0.13	101	0.28	0.14
AV-6	8	0.26	0.15	20	0.22	0.08
AV-1 - Baseline	45	-0.03	0.08	113	-0.01	0.09
AV-3 - Baseline	43	-0.04	0.11	99	-0.01	0.12
AV-6 - Baseline	8	-0.02	0.06	19	-0.03	0.08
Retinol (μg/ml)						
Baseline	50	0.62	0.13	124	0.60	0.15
AV-1	45	0.65	0.15	115	0.61	0.18
AV-3	43	0.65	0.15	101	0.61	0.16
AV-6	8	0.79	0.24	20	0.58	0.10
AV-1 - Baseline	45	0.03	0.11	113	0.01	0.11
AV-3 - Baseline	43	0.04	0.14	99	0.00	0.12
AV-6 – Baseline	8	0.16	0.24	19	0.02	0.12
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	47	127.23	23.78	122	122.39	27.53
AV-1	43	143.30	41.46	111	127.50	26.93
AV-3	39	128.23	25.81	99	129.54	29.97
AV-6	8	121.88	17.63	20	113.20	27.27
AV-1 – Baseline	41	18.83	33.34	108	3.82	21.88
AV-3 – Baseline	38	4.79	25.90	96	4.59	24.17
AV-6 – Baseline	8	6.25	20.07	19	-0.16	18.13
Factor VII C (%)[1]						
Baseline	47	126.96	24.75	122	124.72	24.52
AV-1	43	134.42	24.89	111	123.19	27.23
AV-3	38	130.29	26.44	96	125.69	29.61
AV-6	8	145.00	20.51	20	121.55	34.42
AV-1 – Baseline	41	9.29	19.47	108	-1.48	16.86
AV-3 – Baseline	37	10.27	24.26	93	-0.37	20.28
AV-6 – Baseline	8	26.63	22.58	19	4.21	24.38
Fibrinogen (mg/dl)						
Baseline	47	290.96	62.19	122	298.55	57.06
AV-1	43	286.44	65.15	111	286.46	54.74
AV-3	39	261.67	49.87	97	278.12	62.09
AV-6	8	286.13	63.92	20	303.20	61.51
AV-1 – Baseline	41	-5.37	57.30	108	-13.99	49.10
AV-3 – Baseline	38	-28.50	45.71	94	-20.85	59.12
AV-6 – Baseline	8	-7.38	51.65	19	-16.21	62.83

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.8 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Hormones / Other						
Glucose (mg/dl)						
Baseline	50	105.40	28.34	124	101.58	24.24
AV-1	45	105.78	36.28	115	100.99	22.78
AV-3	44	99.18	23.91	105	99.85	17.93
AV-6	8	96.88	12.99	20	100.30	13.36
AV-1 – Baseline	45	-0.58	12.59	113	-0.92	12.16
AV-3 – Baseline	44	-6.84	13.68	103	-1.80	17.06
AV-6 – Baseline	8	-7.38	18.75	19	-0.53	17.69
Insulin (μIU/ml)						
Baseline	49	12.06	8.12	116	10.70	7.71
AV-1	44	11.75	9.46	109	10.05	7.03
AV-3	39	14.65	12.10	98	11.49	6.68
AV-6	8	12.09	10.38	20	9.20	6.91
AV-1 – Baseline	43	-0.88	5.54	107	-0.43	5.33
AV-3 – Baseline	38	1.49	5.57	91	1.41	7.44
AV-6 – Baseline	8	-0.14	4.78	19	-1.81	7.55
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	50	176.18	84.55	124	146.48	71.67
AV-1	45	197.38	102.02	114	160.58	102.70
AV-3	44	181.20	85.77	105	161.08	130.75
AV-6	8	220.38	91.38	20	149.05	64.88
AV-1 – Baseline	45	19.93	79.99	112	12.00	80.72
AV-3 – Baseline	44	6.02	74.90	103	10.63	111.92
AV-6 – Baseline	8	26.63	119.20	19	16.68	59.91
Total Cholesterol (mg/dl)						
Baseline	50	231.80	32.71	124	222.26	33.71
AV-1	45	219.98	33.82	114	211.69	32.20
AV-3	44	205.23	32.53	105	212.04	32.57
AV-6	8	241.13	49.92	20	215.00	23.94
AV-1 – Baseline	45	-14.82	21.84	112	-10.92	26.78
AV-3 – Baseline	44	-26.86	30.61	103	-10.79	27.89
AV-6 – Baseline	8	9.13	47.78	19	-4.42	30.86
LDL-C (mg/dl)						
Baseline	48	138.19	30.66	123	132.40	30.46
AV-1	44	118.75	35.98	111	120.50	29.88
AV-3	41	110.51	33.70	102	120.71	29.28
AV-6	7	131.71	40.45	20	127.30	24.88
AV-1 – Baseline	42	-22.83	28.41	109	-12.96	27.33
AV-3 – Baseline	40	-30.83	33.68	100	-11.45	28.04
AV-6 – Baseline	7	-2.57	35.04	19	-8.58	32.05
HDL-C (mg/dl)						
Baseline	50	58.50	17.42	124	59.96	16.19
AV-1	45	63.56	18.58	114	60.40	15.75
AV-3	42	59.31	15.70	104	60.29	13.92
AV-6	8	60.50	18.83	20	57.95	11.78
AV-1 – Baseline	45	3.76	8.35	112	0.88	8.49
AV-3 – Baseline	42	1.14	7.01	102	0.26	9.50
AV-6 – Baseline	8	6.00	8.43	19	0.95	8.48

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
HDL-2 (mg/dl)						
Baseline	49	17.73	9.38	123	18.96	8.87
AV-1	44	20.20	9.85	111	20.06	8.55
AV-3	42	16.26	6.76	101	17.19	5.78
AV-6	7	15.57	6.27	20	15.95	5.80
AV-1 – Baseline	43	1.51	6.54	109	1.32	4.52
AV-3 – Baseline	41	-1.71	5.27	98	-1.89	5.65
AV-6 – Baseline	7	-1.00	5.72	19	-0.84	5.24
HDL-3 (mg/dl)						
Baseline	49	40.43	9.13	123	40.78	8.42
AV-1	44	43.39	11.30	112	40.27	7.98
AV-3	42	43.05	9.50	101	43.30	8.71
AV-6	7	47.00	13.67	20	42.00	6.77
AV-1 – Baseline	43	1.95	5.88	110	-0.39	5.94
AV-3 – Baseline	41	3.00	4.86	98	2.16	6.37
AV-6 – Baseline	7	8.29	6.78	19	1.79	6.74
Lp(a) (mg/dl)						
Baseline	50	20.74	14.22	122	19.81	18.78
AV-1	45	16.62	14.70	114	17.31	17.67
AV-3	44	16.14	13.26	101	15.43	14.27
AV-6	8	18.63	8.03	20	26.50	19.24
AV-1 – Baseline	45	-4.73	7.81	111	-3.04	12.22
AV-3 – Baseline	44	-5.20	11.56	99	-3.94	11.05
AV-6 – Baseline	8	4.75	10.12	19	9.21	10.76

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	395	0.07	0.08	282	0.06	0.06
AV-1	343	0.06	0.08	262	0.06	0.07
AV-3	277	0.06	0.08	210	0.05	0.06
AV-6	85	0.06	0.07	77	0.05	0.04
AV-1 - Baseline	334	-0.00	0.06	257	-0.00	0.05
AV-3 - Baseline	269	-0.01	0.08	206	-0.00	0.06
AV-6 – Baseline	85	-0.01	0.08	74	-0.01	0.04
Beta-Carotene (µg/ml)						
Baseline	394	0.36	0.38	282	0.30	0.25
AV-1	342	0.35	0.37	263	0.29	0.26
AV-3	277	0.34	0.44	210	0.27	0.22
AV-6	85	0.35	0.32	77	0.26	0.19
AV-1 - Baseline	333	-0.01	0.21	258	-0.02	0.19
AV-3 - Baseline	268	-0.02	0.33	206	-0.03	0.22
AV-6 – Baseline	85	0.01	0.27	74	-0.01	0.19
Alpha-tocopherol (µg/ml)						
Baseline	395	14.36	6.52	282	14.39	6.35
AV-1	343	14.37	5.40	263	14.66	6.56
AV-3	277	14.75	6.09	210	15.42	6.67
AV-6	85	16.24	7.89	77	14.57	6.11
AV-1 - Baseline	334	0.12	5.07	258	0.06	5.05
AV-3 - Baseline	269	0.63	5.98	206	1.06	6.24
AV-6 – Baseline	85	2.95	6.76	74	1.04	4.90
Gamma-tocopherol (µg/ml)						
Baseline	395	2.50	1.38	282	2.53	1.42
AV-1	343	2.33	1.38	263	2.29	1.31
AV-3	277	2.14	1.32	210	2.19	1.55
AV-6	85	2.10	1.29	77	2.31	1.63
AV-1 - Baseline	334	-0.17	0.91	258	-0.21	0.94
AV-3 - Baseline	269	-0.32	1.11	206	-0.35	1.11
AV-6 – Baseline	85	-0.45	1.21	74	-0.40	1.15
Beta-Cryptoxanthine (µg/ml)						
Baseline	395	0.09	0.06	282	0.09	0.07
AV-1	343	0.09	0.07	263	0.09	0.06
AV-3	277	0.09	0.06	210	0.09	0.08
AV-6	85	0.10	0.13	77	0.10	0.08
AV-1 - Baseline	334	0.00	0.06	258	-0.00	0.06
AV-3 - Baseline	269	0.00	0.05	206	0.01	0.08
AV-6 – Baseline	85	0.01	0.12	74	0.02	0.08
Lycopene (µg/ml)						
Baseline	395	0.39	0.21	282	0.40	0.21
AV-1	343	0.38	0.21	263	0.38	0.21
AV-3	277	0.34	0.21	210	0.35	0.20
AV-6	85	0.38	0.22	77	0.33	0.21
AV-1 - Baseline	334	-0.00	0.18	258	-0.02	0.19
AV-3 - Baseline	269	-0.04	0.22	206	-0.04	0.21
AV-6 – Baseline	85	-0.00	0.26	74	-0.07	0.22

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lutein and Zeaxanthin (μg/ml)						
Baseline	395	0.24	0.12	282	0.23	0.11
AV-1	343	0.25	0.12	263	0.24	0.11
AV-3	277	0.22	0.11	210	0.21	0.09
AV-6	85	0.25	0.28	77	0.20	0.09
AV-1 - Baseline	334	0.00	0.08	258	0.01	0.08
AV-3 - Baseline	269	-0.02	0.10	206	-0.01	0.08
AV-6 – Baseline	85	-0.02	0.24	74	-0.04	0.11
Retinol (μg/ml)						
Baseline	395	0.56	0.16	282	0.56	0.16
AV-1	343	0.57	0.15	263	0.57	0.15
AV-3	277	0.55	0.16	210	0.57	0.18
AV-6	85	0.58	0.14	77	0.56	0.17
AV-1 - Baseline	334	0.01	0.10	258	0.01	0.08
AV-3 - Baseline	269	0.00	0.12	206	0.01	0.14
AV-6 – Baseline	85	0.05	0.13	74	0.03	0.14
Clotting Factor						
Factor VII Activity, Antigen (%)	383	113.26	22.95	268	113.54	26.49
Baseline	334	119.15	28.31	254	118.29	30.43
AV-1	263	119.24	26.86	201	118.50	30.52
AV-3	88	109.35	23.64	69	101.93	24.39
AV-6	317	5.64	20.62	239	4.70	18.58
AV-1 – Baseline	248	5.33	24.05	187	5.32	22.17
AV-3 – Baseline	84	0.01	21.54	64	-3.64	15.93
AV-6 – Baseline						
Factor VII C (%)[1]						
Baseline	373	117.99	28.00	262	116.98	29.20
AV-1	330	119.30	27.11	253	115.93	27.30
AV-3	262	118.56	26.64	200	118.55	30.82
AV-6	88	126.81	31.57	69	121.54	31.64
AV-1 – Baseline	303	1.76	19.50	232	-1.88	20.49
AV-3 – Baseline	238	0.88	23.24	181	0.34	25.85
AV-6 – Baseline	81	9.16	29.61	62	6.37	31.46
Fibrinogen (mg/dl)						
Baseline	382	328.07	66.21	268	318.81	65.87
AV-1	333	323.92	66.78	254	314.64	64.60
AV-3	263	309.23	68.37	200	303.78	63.64
AV-6	88	313.64	67.04	69	318.52	72.52
AV-1 – Baseline	316	-2.01	52.20	239	-4.26	47.77
AV-3 – Baseline	247	-20.76	54.67	186	-12.24	67.63
AV-6 – Baseline	83	-12.37	51.39	64	-4.55	70.37

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.8 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Hormones / Other						
Glucose (mg/dl)						
Baseline	394	111.38	42.90	283	106.94	38.02
AV-1	343	108.62	40.78	261	109.82	41.39
AV-3	285	106.09	34.83	212	109.56	43.65
AV-6	88	100.88	25.23	78	107.64	46.91
AV-1 – Baseline	333	-1.14	36.72	256	0.63	26.09
AV-3 – Baseline	276	-4.66	33.56	208	0.45	26.72
AV-6 – Baseline	88	-3.15	33.63	75	4.72	27.97
Insulin (μIU/ml)						
Baseline	386	15.99	25.09	279	13.16	8.24
AV-1	341	14.38	13.52	261	13.18	7.77
AV-3	272	17.02	26.17	204	14.58	9.73
AV-6	88	17.82	57.84	78	11.61	7.05
AV-1 – Baseline	324	-0.86	8.40	253	-0.14	6.24
AV-3 – Baseline	258	-1.47	20.54	197	1.85	8.48
AV-6 – Baseline	86	-2.34	17.59	75	-0.47	6.94
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	395	119.97	54.59	283	118.84	60.74
AV-1	343	122.01	50.37	263	119.79	59.57
AV-3	285	118.81	47.05	212	122.05	61.76
AV-6	88	120.25	46.63	78	115.62	64.16
AV-1 – Baseline	334	4.30	38.53	258	-2.10	39.83
AV-3 – Baseline	277	1.57	44.04	208	0.17	53.05
AV-6 – Baseline	88	0.41	48.95	75	-0.40	48.54
Total Cholesterol (mg/dl)						
Baseline	395	224.05	42.33	283	221.35	41.99
AV-1	343	220.02	41.01	263	214.95	38.34
AV-3	285	213.20	39.38	212	212.66	39.24
AV-6	88	208.84	36.33	78	213.40	38.98
AV-1 – Baseline	334	-4.89	29.09	258	-6.82	24.91
AV-3 – Baseline	277	-11.16	35.55	208	-7.24	29.90
AV-6 – Baseline	88	-17.02	36.17	75	-3.72	41.74
LDL-C (mg/dl)						
Baseline	394	143.33	40.35	281	140.54	38.87
AV-1	343	134.12	39.02	260	132.36	37.67
AV-3	285	129.85	37.28	210	132.45	39.04
AV-6	88	124.56	34.14	77	133.16	34.49
AV-1 – Baseline	334	-9.86	27.40	255	-8.78	22.85
AV-3 – Baseline	276	-13.98	33.50	206	-6.74	28.22
AV-6 – Baseline	87	-19.62	35.56	74	-4.11	39.13
HDL-C (mg/dl)						
Baseline	394	56.73	13.77	282	56.71	13.47
AV-1	343	61.44	15.73	263	59.24	14.51
AV-3	285	59.56	14.93	212	56.39	13.80
AV-6	88	60.30	14.04	78	57.58	13.82
AV-1 – Baseline	334	4.08	9.64	257	2.60	8.37
AV-3 – Baseline	276	2.43	10.02	208	0.08	8.35
AV-6 – Baseline	87	2.30	11.35	75	1.16	9.87

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
HDL-2 (mg/dl)						
Baseline	392	17.52	7.15	276	17.12	7.17
AV-1	341	20.25	8.62	261	18.81	8.19
AV-3	280	16.74	5.98	210	15.25	5.21
AV-6	88	16.75	5.73	77	15.84	5.59
AV-1 – Baseline	330	2.25	5.46	250	1.58	5.16
AV-3 – Baseline	271	-1.15	5.69	202	-1.43	5.15
AV-6 – Baseline	87	-0.84	6.76	71	-1.04	5.74
HDL-3 (mg/dl)						
Baseline	392	39.20	8.14	276	39.55	7.49
AV-1	343	41.26	9.00	261	40.23	7.78
AV-3	280	42.95	9.85	210	40.98	9.38
AV-6	88	43.55	9.48	77	41.81	9.32
AV-1 – Baseline	331	1.80	5.81	250	0.74	4.84
AV-3 – Baseline	271	3.55	6.89	202	1.42	6.49
AV-6 – Baseline	87	3.14	7.26	71	1.94	7.16
Lp(a) (mg/dl)						
Baseline	388	40.45	31.50	277	38.83	28.83
AV-1	341	38.48	31.37	262	37.15	27.76
AV-3	278	34.82	26.70	210	31.56	22.98
AV-6	87	44.77	26.76	75	42.75	25.73
AV-1 – Baseline	327	-1.15	13.04	252	-2.08	10.95
AV-3 – Baseline	265	-4.26	21.71	200	-4.45	19.03
AV-6 – Baseline	85	8.78	19.81	69	10.64	19.36

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (μg/ml)						
Baseline	177	0.09	0.11	222	0.10	0.09
AV-1	148	0.08	0.06	185	0.09	0.07
AV-3	131	0.07	0.08	172	0.07	0.07
AV-6	36	0.06	0.05	48	0.08	0.07
AV-1 - Baseline	144	-0.02	0.11	183	-0.01	0.08
AV-3 - Baseline	129	-0.03	0.12	171	-0.03	0.09
AV-6 – Baseline	33	-0.01	0.07	47	-0.00	0.06
Beta-Carotene (μg/ml)						
Baseline	177	0.32	0.49	222	0.32	0.31
AV-1	148	0.27	0.26	185	0.28	0.23
AV-3	131	0.23	0.24	172	0.28	0.27
AV-6	36	0.25	0.25	48	0.28	0.19
AV-1 - Baseline	144	-0.07	0.38	183	-0.05	0.25
AV-3 - Baseline	129	-0.11	0.41	171	-0.06	0.35
AV-6 – Baseline	33	0.01	0.14	47	-0.08	0.37
Alpha-tocopherol (μg/ml)						
Baseline	177	15.52	7.30	222	15.78	6.81
AV-1	148	16.91	7.56	185	16.56	7.41
AV-3	131	16.10	7.06	172	17.17	8.25
AV-6	36	19.07	9.72	48	19.13	12.44
AV-1 - Baseline	144	1.42	6.23	183	0.76	5.12
AV-3 - Baseline	129	0.08	6.53	171	1.39	6.61
AV-6 – Baseline	33	3.85	10.16	47	3.10	7.60
Gamma-tocopherol (μg/ml)						
Baseline	177	2.29	1.37	222	2.23	1.37
AV-1	148	2.12	1.44	185	1.96	1.33
AV-3	131	1.99	1.23	172	1.90	1.46
AV-6	36	1.81	0.97	48	1.77	1.21
AV-1 - Baseline	144	-0.22	0.98	183	-0.28	0.95
AV-3 - Baseline	129	-0.33	1.11	171	-0.41	1.19
AV-6 – Baseline	33	-0.74	1.03	47	-0.42	1.42
Beta-Cryptoxanthine (μg/ml)						
Baseline	177	0.12	0.17	222	0.12	0.11
AV-1	148	0.11	0.11	185	0.12	0.11
AV-3	131	0.11	0.08	172	0.12	0.10
AV-6	36	0.11	0.13	48	0.12	0.08
AV-1 - Baseline	144	-0.02	0.15	183	-0.01	0.09
AV-3 - Baseline	129	-0.01	0.10	171	-0.01	0.10
AV-6 – Baseline	33	0.03	0.11	47	0.00	0.08
Lycopene (μg/ml)						
Baseline	177	0.40	0.19	222	0.45	0.21
AV-1	148	0.38	0.18	185	0.40	0.19
AV-3	131	0.35	0.19	172	0.38	0.19
AV-6	36	0.41	0.25	48	0.42	0.22
AV-1 - Baseline	144	-0.03	0.15	183	-0.05	0.17
AV-3 - Baseline	129	-0.05	0.18	171	-0.09	0.21
AV-6 – Baseline	33	-0.02	0.21	47	-0.04	0.27

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lutein and Zeaxanthin (μg/ml)						
Baseline	177	0.19	0.09	222	0.22	0.10
AV-1	148	0.20	0.09	185	0.22	0.11
AV-3	131	0.19	0.08	172	0.20	0.10
AV-6	36	0.19	0.11	48	0.21	0.11
AV-1 - Baseline	144	0.00	0.06	183	-0.01	0.08
AV-3 - Baseline	129	-0.01	0.07	171	-0.03	0.08
AV-6 – Baseline	33	0.02	0.09	47	-0.03	0.09
Retinol (μg/ml)						
Baseline	177	0.53	0.13	222	0.56	0.14
AV-1	148	0.55	0.13	185	0.56	0.15
AV-3	131	0.54	0.12	172	0.56	0.13
AV-6	36	0.59	0.16	48	0.58	0.16
AV-1 - Baseline	144	0.02	0.08	183	-0.00	0.09
AV-3 - Baseline	129	0.00	0.11	171	-0.01	0.11
AV-6 – Baseline	33	0.06	0.14	47	0.03	0.11
Clotting Factor						
Factor VII Activity, Antigen (%)	170	122.91	25.34	209	124.94	27.93
Baseline	134	128.32	26.46	179	129.13	28.73
AV-1	131	130.02	28.85	160	130.24	28.89
AV-3	36	122.14	28.37	46	116.24	22.07
AV-6	124	9.34	24.44	168	4.43	22.81
AV-1 – Baseline	124	7.00	28.34	152	4.43	27.75
AV-3 – Baseline	32	1.72	26.92	43	-5.33	18.63
AV-6 – Baseline						
Factor VII C (%)[1]						
Baseline	164	126.37	29.10	202	124.85	27.65
AV-1	131	126.92	24.66	174	123.49	26.08
AV-3	132	127.88	26.97	159	125.45	29.92
AV-6	36	144.14	28.08	47	133.79	30.20
AV-1 – Baseline	118	3.15	26.69	158	-0.80	19.87
AV-3 – Baseline	120	2.67	28.07	146	0.18	27.02
AV-6 – Baseline	30	16.87	29.54	40	6.33	21.44
Fibrinogen (mg/dl)						
Baseline	170	318.05	66.36	209	316.09	63.72
AV-1	134	311.28	60.61	178	315.65	61.87
AV-3	132	303.35	65.58	161	303.29	64.07
AV-6	36	296.83	62.69	47	296.79	62.73
AV-1 – Baseline	124	-5.34	54.42	167	-6.71	52.31
AV-3 – Baseline	125	-15.50	55.30	153	-14.54	55.87
AV-6 – Baseline	32	-4.91	64.36	43	-15.98	49.66

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.8 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Hormones / Other						
Glucose (mg/dl)						
Baseline	176	104.09	30.87	222	106.05	35.26
AV-1	148	106.64	36.96	185	104.92	30.63
AV-3	135	105.76	28.81	175	107.99	37.48
AV-6	37	121.57	47.80	48	106.29	28.62
AV-1 – Baseline	142	2.91	23.64	183	-1.09	17.83
AV-3 – Baseline	132	-0.22	25.85	174	-1.05	22.27
AV-6– Baseline	34	11.97	32.11	47	-2.17	18.62
Insulin (μIU/ml)						
Baseline	174	14.00	8.69	220	13.60	7.88
AV-1	146	13.73	9.11	182	13.21	6.62
AV-3	125	15.41	8.78	168	13.65	7.38
AV-6	37	16.47	16.58	48	10.86	6.54
AV-1 – Baseline	140	-0.39	6.26	180	-0.41	6.00
AV-6 – Baseline	122	1.75	7.31	166	-0.26	7.90
AV-3 – Baseline	34	0.36	15.47	47	-2.00	8.19
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	178	162.16	67.43	222	166.98	86.24
AV-1	148	169.21	67.99	185	181.77	123.47
AV-3	134	168.77	65.99	175	188.90	139.45
AV-6	37	179.59	55.69	48	190.52	102.49
AV-1 – Baseline	144	8.65	51.64	183	14.21	94.14
AV-3 – Baseline	132	1.16	64.12	174	23.11	107.54
AV-6 – Baseline	34	3.97	60.50	47	16.72	88.64
Total Cholesterol (mg/dl)						
Baseline	178	219.26	37.88	222	224.51	37.44
AV-1	148	212.66	34.96	185	215.15	35.35
AV-3	134	207.70	33.57	175	214.32	36.09
AV-6	37	214.59	42.07	48	216.52	37.37
AV-1 – Baseline	144	-6.39	27.28	183	-11.76	23.84
AV-3 – Baseline	132	-11.09	33.70	174	-11.10	28.83
AV-6 – Baseline	34	-6.12	42.49	47	-14.34	35.31
LDL-C (mg/dl)						
Baseline	176	132.35	32.60	216	137.42	35.02
AV-1	147	122.43	31.51	178	127.15	33.73
AV-3	133	118.17	29.26	166	125.19	34.54
AV-6	37	122.51	35.19	47	125.98	37.46
AV-1 – Baseline	141	-9.70	26.16	174	-14.01	24.32
AV-3 – Baseline	130	-13.22	30.18	162	-13.96	28.27
AV-6 – Baseline	34	-10.79	36.03	45	-19.73	36.89
HDL-C (mg/dl)						
Baseline	177	54.01	12.96	222	53.64	14.08
AV-1	148	56.93	14.89	185	53.79	13.04
AV-3	133	55.62	14.45	175	54.27	13.73
AV-6	37	56.16	15.95	48	52.42	12.94
AV-1 – Baseline	143	2.54	9.43	183	0.64	7.14
AV-3 – Baseline	131	1.98	10.12	174	0.99	8.84
AV-6 – Baseline	34	3.94	11.70	47	0.79	10.52

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
HDL-2 (mg/dl)						
Baseline	177	15.97	6.45	218	15.61	6.68
AV-1	147	17.88	7.89	185	16.59	6.73
AV-3	132	15.33	6.04	174	15.22	5.68
AV-6	36	15.58	6.92	48	14.92	6.71
AV-1 – Baseline	142	1.36	5.25	180	0.89	4.43
AV-3 – Baseline	130	-0.62	5.54	170	-0.44	5.35
AV-6 – Baseline	33	1.52	5.31	45	0.09	8.13
HDL-3 (mg/dl)						
Baseline	177	38.03	7.75	218	37.58	7.65
AV-1	147	39.03	8.12	185	37.19	7.57
AV-3	132	40.17	9.27	174	39.08	8.82
AV-6	36	40.69	10.34	48	37.50	8.49
AV-1 – Baseline	142	1.18	5.43	180	-0.31	4.77
AV-3 – Baseline	130	2.59	6.66	170	1.57	6.25
AV-6 – Baseline	33	2.33	7.90	45	0.80	5.70
Lp(a) (mg/dl)						
Baseline	175	17.59	17.80	222	21.97	22.40
AV-1	145	16.40	17.78	184	19.75	20.96
AV-3	128	14.54	15.45	174	21.05	21.93
AV-6	37	18.95	15.01	48	29.46	21.51
AV-1 – Baseline	140	-0.73	7.22	182	-1.79	10.78
AV-3 – Baseline	125	-0.93	8.52	173	-2.46	13.69
AV-6 – Baseline	33	4.03	13.68	47	8.11	16.95

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: White Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (μg/ml)						
Baseline	484	0.07	0.06	777	0.09	0.08
AV-1	436	0.06	0.05	749	0.08	0.08
AV-3	392	0.06	0.05	675	0.07	0.08
AV-6	131	0.05	0.04	203	0.08	0.08
AV-1 - Baseline	427	-0.01	0.05	727	-0.01	0.06
AV-3 - Baseline	386	-0.01	0.05	655	-0.02	0.07
AV-6 – Baseline	129	-0.02	0.08	195	-0.02	0.06
Beta-Carotene (μg/ml)						
Baseline	484	0.27	0.22	777	0.34	0.34
AV-1	436	0.24	0.22	749	0.31	0.31
AV-3	392	0.23	0.21	675	0.32	0.40
AV-6	131	0.25	0.27	203	0.32	0.34
AV-1 - Baseline	427	-0.02	0.20	727	-0.04	0.21
AV-3 - Baseline	386	-0.04	0.22	655	-0.03	0.32
AV-6 – Baseline	129	-0.03	0.24	195	-0.02	0.32
Alpha-tocopherol (μg/ml)						
Baseline	484	16.18	6.94	777	16.52	7.83
AV-1	436	18.04	9.19	749	17.02	7.36
AV-3	392	18.14	8.42	675	18.60	8.03
AV-6	131	18.94	8.31	203	19.04	8.50
AV-1 - Baseline	427	1.86	6.39	727	0.54	5.80
AV-3 - Baseline	386	2.00	6.87	655	2.14	7.31
AV-6 – Baseline	129	3.59	8.41	195	3.60	8.14
Gamma-tocopherol (μg/ml)						
Baseline	484	2.51	1.70	777	2.22	1.40
AV-1	436	2.23	1.91	749	1.80	1.21
AV-3	392	2.00	1.53	675	1.60	1.17
AV-6	131	1.81	1.46	203	1.66	1.39
AV-1 - Baseline	427	-0.32	1.15	727	-0.40	0.92
AV-3 - Baseline	386	-0.59	1.20	655	-0.62	1.18
AV-6 – Baseline	129	-0.66	1.70	195	-0.67	1.35
Beta-Cryptoxanthine (μg/ml)						
Baseline	484	0.08	0.07	777	0.09	0.07
AV-1	436	0.07	0.06	748	0.08	0.07
AV-3	392	0.08	0.06	675	0.09	0.08
AV-6	131	0.09	0.07	203	0.10	0.08
AV-1 - Baseline	427	-0.00	0.04	726	-0.01	0.06
AV-3 - Baseline	386	-0.00	0.07	655	0.00	0.07
AV-6 – Baseline	129	0.01	0.07	195	0.01	0.08
Lycopene (μg/ml)						
Baseline	484	0.40	0.20	777	0.41	0.19
AV-1	436	0.39	0.19	749	0.40	0.19
AV-3	392	0.35	0.18	675	0.39	0.21
AV-6	131	0.36	0.20	203	0.36	0.19
AV-1 - Baseline	427	-0.01	0.17	727	-0.01	0.17
AV-3 - Baseline	386	-0.05	0.20	655	-0.02	0.22
AV-6 – Baseline	129	-0.00	0.21	195	-0.05	0.22

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: White Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lutein and Zeaxanthin (μg/ml)						
Baseline	484	0.19	0.09	777	0.20	0.09
AV-1	436	0.20	0.09	749	0.21	0.09
AV-3	392	0.18	0.10	675	0.19	0.09
AV-6	131	0.16	0.08	203	0.18	0.09
AV-1 - Baseline	427	0.00	0.06	727	0.00	0.06
AV-3 - Baseline	386	-0.01	0.07	655	-0.02	0.08
AV-6 – Baseline	129	-0.03	0.07	195	-0.03	0.09
Retinol (μg/ml)						
Baseline	484	0.61	0.14	777	0.61	0.15
AV-1	436	0.64	0.15	749	0.62	0.14
AV-3	392	0.63	0.15	675	0.61	0.16
AV-6	131	0.66	0.16	203	0.64	0.16
AV-1 - Baseline	427	0.03	0.11	727	0.01	0.10
AV-3 - Baseline	386	0.02	0.14	655	0.00	0.13
AV-6 – Baseline	129	0.06	0.15	195	0.06	0.14
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	466	130.54	29.03	756	124.77	28.36
AV-1	413	142.32	35.17	722	131.17	31.02
AV-3	376	138.26	34.17	640	129.30	31.81
AV-6	128	130.31	31.34	197	117.58	27.48
AV-1 – Baseline	398	10.84	25.67	684	6.24	23.02
AV-3 – Baseline	359	8.49	31.68	604	4.90	28.90
AV-6 – Baseline	124	3.06	29.78	189	-3.53	25.40
Factor VII C (%)[1]						
Baseline	463	131.66	27.89	750	126.27	26.73
AV-1	409	139.00	32.05	717	126.12	27.93
AV-3	373	137.63	35.06	638	128.37	32.32
AV-6	127	150.85	40.17	197	133.37	32.32
AV-1 – Baseline	392	6.86	24.44	673	-0.44	22.25
AV-3 – Baseline	355	8.19	29.83	597	2.47	27.85
AV-6 – Baseline	121	18.63	33.87	188	6.86	28.44
Fibrinogen (mg/dl)						
Baseline	464	310.11	62.68	754	304.41	57.78
AV-1	412	298.22	59.62	720	296.60	58.17
AV-3	375	292.31	56.92	640	289.16	55.70
AV-6	128	284.21	52.37	198	287.96	53.30
AV-1 – Baseline	395	-13.02	52.01	680	-8.11	53.98
AV-3 – Baseline	356	-17.45	62.90	602	-15.36	55.00
AV-6 – Baseline	124	-26.53	60.25	190	-12.93	52.76

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.8 (continued)
Blood Specimen Analysis: White Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Hormones / Other						
Glucose (mg/dl)						
Baseline	483	104.40	34.60	773	99.20	23.96
AV-1	434	101.79	29.67	747	96.81	20.23
AV-3	397	101.26	31.41	680	96.65	21.96
AV-6	131	102.31	25.25	204	97.84	22.89
AV-1 – Baseline	425	-3.37	18.03	721	-2.36	15.78
AV-3 – Baseline	391	-3.65	25.01	658	-2.96	19.40
AV-6 – Baseline	129	-0.25	17.73	194	-1.31	17.30
Insulin (μIU/ml)						
Baseline	473	12.47	7.13	742	11.11	6.52
AV-1	423	11.81	7.05	712	11.10	7.09
AV-3	377	13.09	7.79	640	12.10	6.92
AV-6	131	10.81	7.52	203	11.33	23.15
AV-1 – Baseline	407	-0.75	5.63	672	-0.05	5.48
AV-3 – Baseline	364	0.73	6.63	594	1.02	6.24
AV-6 – Baseline	129	-1.50	6.76	190	1.02	20.07
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	484	167.85	104.44	776	148.16	75.10
AV-1	434	182.58	141.40	749	150.75	70.94
AV-3	397	175.48	84.11	678	154.09	75.87
AV-6	131	178.21	77.23	202	154.15	64.36
AV-1 – Baseline	425	14.68	77.27	726	2.85	53.61
AV-3 – Baseline	389	8.18	86.64	657	6.45	61.17
AV-6 – Baseline	129	2.19	145.70	194	9.41	62.77
Total Cholesterol (mg/dl)						
Baseline	484	230.56	41.19	776	225.46	36.16
AV-1	434	224.01	40.78	749	216.15	34.81
AV-3	397	220.18	36.49	678	215.45	34.61
AV-6	131	211.94	39.01	202	215.58	34.96
AV-1 – Baseline	425	-6.00	30.26	726	-8.92	28.82
AV-3 – Baseline	389	-10.38	34.34	657	-8.72	32.34
AV-6 – Baseline	129	-18.41	42.56	194	-10.37	36.97
LDL-C (mg/dl)						
Baseline	469	142.35	36.70	760	138.85	31.99
AV-1	418	128.17	35.47	738	126.68	31.58
AV-3	383	127.25	34.60	668	126.63	32.02
AV-6	128	120.04	36.73	201	125.92	32.49
AV-1 – Baseline	405	-13.65	27.27	708	-11.57	25.97
AV-3 – Baseline	368	-15.45	31.83	636	-10.96	29.64
AV-6 – Baseline	121	-22.65	40.16	190	-12.28	35.66
HDL-C (mg/dl)						
Baseline	480	55.47	14.64	772	57.06	14.40
AV-1	432	59.82	17.04	749	59.39	14.95
AV-3	393	58.67	16.90	676	58.57	15.43
AV-6	131	57.36	14.88	202	58.73	14.31
AV-1 – Baseline	422	4.19	9.38	722	2.38	8.17
AV-3 – Baseline	383	3.10	10.39	651	1.49	9.62
AV-6 – Baseline	128	1.96	12.37	194	-0.31	9.75

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: White Women

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
HDL-2 (mg/dl)						
Baseline	459	16.89	7.60	743	17.89	7.59
AV-1	415	19.30	8.87	721	19.21	8.14
AV-3	387	16.54	6.97	662	16.45	6.55
AV-6	131	16.27	6.26	202	16.71	6.10
AV-1 – Baseline	390	2.06	4.96	672	1.17	4.63
AV-3 – Baseline	363	-0.52	5.55	615	-1.63	5.38
AV-6 – Baseline	125	0.74	6.85	186	-1.11	6.69
HDL-3 (mg/dl)						
Baseline	459	38.70	8.48	743	39.14	8.18
AV-1	415	40.84	9.58	721	40.25	8.24
AV-3	387	42.02	10.82	662	42.00	9.48
AV-6	131	41.08	10.03	202	42.01	9.22
AV-1 – Baseline	390	2.17	5.79	672	1.18	5.24
AV-3 – Baseline	363	3.64	7.46	615	2.96	6.67
AV-6– Baseline	125	1.18	8.51	186	0.76	6.99
Lp(a) (mg/dl)						
Baseline	472	25.65	25.24	764	26.46	27.75
AV-1	426	24.39	26.22	737	24.42	27.46
AV-3	382	21.06	21.07	651	21.94	23.42
AV-6	131	29.03	21.50	204	30.39	23.74
AV-1 – Baseline	410	-1.06	10.74	705	-1.96	10.80
AV-3 – Baseline	368	-4.58	14.45	623	-4.39	14.78
AV-6 – Baseline	127	5.20	18.14	193	6.48	14.60

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: Unknown Race/Ethnicity

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (μg/ml)						
Baseline	25	0.10	0.05	33	0.11	0.13
AV-1	23	0.10	0.09	29	0.09	0.10
AV-3	19	0.09	0.07	25	0.07	0.08
AV-6	4	0.04	0.02	9	0.08	0.05
AV-1 - Baseline	23	0.00	0.07	28	-0.03	0.05
AV-3 - Baseline	19	-0.01	0.06	24	-0.05	0.08
AV-6 – Baseline	4	-0.06	0.07	9	-0.03	0.07
Beta-Carotene (μg/ml)						
Baseline	25	0.35	0.32	33	0.42	0.45
AV-1	23	0.35	0.25	29	0.35	0.31
AV-3	19	0.36	0.45	25	0.36	0.33
AV-6	4	0.25	0.26	9	0.47	0.26
AV-1 - Baseline	23	-0.03	0.16	28	-0.07	0.29
AV-3 - Baseline	19	0.01	0.22	24	-0.03	0.20
AV-6 – Baseline	4	-0.10	0.11	9	-0.20	0.45
Alpha-tocopherol (μg/ml)						
Baseline	25	17.48	8.26	33	16.71	7.64
AV-1	23	18.94	11.06	29	17.21	6.22
AV-3	19	19.93	10.62	25	18.06	6.86
AV-6	4	17.55	6.71	9	21.07	7.45
AV-1 - Baseline	23	0.97	5.11	28	0.09	5.64
AV-3 - Baseline	19	1.50	5.54	24	0.12	5.17
AV-6 – Baseline	4	0.11	11.11	9	2.18	6.79
Gamma-tocopherol (μg/ml)						
Baseline	25	2.19	1.14	33	1.90	1.08
AV-1	23	2.00	0.87	29	1.73	1.06
AV-3	19	1.65	1.06	25	1.50	0.95
AV-6	4	1.72	1.10	9	0.84	0.58
AV-1 - Baseline	23	-0.14	0.99	28	-0.08	0.70
AV-3 - Baseline	19	-0.43	1.36	24	-0.42	0.78
AV-6 – Baseline	4	-0.56	2.31	9	-0.78	0.83
Beta-Cryptoxanthine (μg/ml)						
Baseline	25	0.09	0.08	33	0.11	0.12
AV-1	23	0.11	0.07	29	0.08	0.06
AV-3	19	0.09	0.08	25	0.13	0.24
AV-6	4	0.09	0.07	9	0.15	0.12
AV-1 - Baseline	23	0.01	0.05	28	-0.02	0.08
AV-3 - Baseline	19	0.01	0.04	24	0.02	0.23
AV-6 – Baseline	4	-0.03	0.10	9	0.03	0.13
Lycopene (μg/ml)						
Baseline	25	0.48	0.21	33	0.36	0.21
AV-1	23	0.44	0.23	29	0.33	0.22
AV-3	19	0.30	0.12	25	0.29	0.20
AV-6	4	0.49	0.19	9	0.30	0.13
AV-1 - Baseline	23	-0.06	0.24	28	-0.00	0.16
AV-3 - Baseline	19	-0.15	0.18	24	-0.04	0.15
AV-6 – Baseline	4	-0.16	0.50	9	-0.04	0.11

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: Unknown Race/Ethnicity

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lutein and Zeaxanthin (μg/ml)						
Baseline	25	0.20	0.10	33	0.20	0.14
AV-1	23	0.20	0.11	29	0.22	0.12
AV-3	19	0.20	0.11	25	0.19	0.11
AV-6	4	0.18	0.06	9	0.18	0.05
AV-1 - Baseline	23	-0.01	0.07	28	0.01	0.10
AV-3 - Baseline	19	-0.00	0.10	24	-0.03	0.10
AV-6 – Baseline	4	-0.06	0.03	9	-0.02	0.09
Retinol (μg/ml)						
Baseline	25	0.59	0.14	33	0.58	0.13
AV-1	23	0.64	0.19	29	0.60	0.13
AV-3	19	0.59	0.12	25	0.60	0.14
AV-6	4	0.62	0.16	9	0.68	0.14
AV-1 - Baseline	23	0.06	0.13	28	0.00	0.12
AV-3 - Baseline	19	0.02	0.11	24	0.03	0.12
AV-6 – Baseline	4	-0.05	0.10	9	0.07	0.12
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	25	124.88	22.36	33	120.91	21.99
AV-1	23	133.00	26.98	28	130.21	27.60
AV-3	18	133.94	22.92	24	131.13	27.89
AV-6	4	121.25	4.50	9	108.44	31.62
AV-1 – Baseline	23	8.43	26.66	28	8.82	16.06
AV-3 – Baseline	18	12.06	23.28	24	7.96	22.40
AV-6 – Baseline	4	-8.50	10.02	9	-22.00	28.00
Factor VII C (%)[1]						
Baseline	24	123.79	22.90	33	123.64	21.38
AV-1	23	130.57	20.25	28	127.11	27.36
AV-3	18	146.94	30.04	24	130.25	31.96
AV-6	4	132.50	16.54	9	128.67	37.48
AV-1 – Baseline	22	7.41	19.63	28	3.71	18.73
AV-3 – Baseline	17	23.35	20.64	24	4.83	29.02
AV-6 – Baseline	4	9.25	17.69	9	-2.22	21.98
Fibrinogen (mg/dl)						
Baseline	25	317.08	55.39	33	324.70	71.74
AV-1	23	294.04	64.72	28	307.32	59.63
AV-3	18	293.56	77.70	24	289.58	72.57
AV-6	4	272.50	27.38	9	279.89	50.05
AV-1 – Baseline	23	-24.48	53.87	28	-23.04	51.03
AV-3 – Baseline	18	-20.67	73.91	24	-35.75	51.57
AV-6 – Baseline	4	-13.25	10.50	9	-12.56	55.32

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.8 (continued)
Blood Specimen Analysis: Unknown Race/Ethnicity

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Hormones / Other						
Glucose (mg/dl)						
Baseline	25	98.32	19.88	34	100.62	26.89
AV-1	23	103.04	28.07	29	99.59	19.11
AV-3	19	103.37	26.24	25	100.44	19.40
AV-6	4	97.00	4.55	9	114.89	30.46
AV-1 – Baseline	23	4.17	14.54	29	-2.83	14.46
AV-3 – Baseline	19	8.58	15.90	25	-2.96	17.19
AV-6 – Baseline	4	4.25	8.96	9	-1.67	26.90
Insulin (μIU/ml)						
Baseline	25	10.15	6.58	34	10.24	4.97
AV-1	23	10.90	7.41	29	10.97	6.59
AV-3	19	12.14	6.86	23	11.93	3.80
AV-6	4	12.48	2.45	9	12.22	7.46
AV-1 – Baseline	23	0.61	6.25	29	0.11	3.45
AV-3 – Baseline	19	2.98	5.27	23	1.24	4.19
AV-6 – Baseline	4	4.23	4.01	9	2.61	5.84
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	25	155.40	89.00	34	157.29	73.88
AV-1	23	168.13	68.18	29	161.72	75.02
AV-3	19	155.11	63.58	25	153.68	61.62
AV-6	4	144.75	42.03	9	156.22	79.97
AV-1 – Baseline	23	11.57	62.43	29	2.21	38.74
AV-3 – Baseline	19	8.42	31.67	25	-12.04	52.04
AV-6 – Baseline	4	7.75	35.86	9	-19.67	76.67
Total Cholesterol (mg/dl)						
Baseline	25	238.76	41.89	34	221.15	35.46
AV-1	23	236.48	36.92	29	220.34	38.73
AV-3	19	219.95	38.86	25	222.88	36.73
AV-6	4	229.75	21.50	9	195.67	25.20
AV-1 – Baseline	23	-4.96	28.61	29	-1.17	29.84
AV-3 – Baseline	19	-12.16	34.25	25	-4.80	29.40
AV-6 – Baseline	4	-31.25	36.31	9	-31.67	29.23
LDL-C (mg/dl)						
Baseline	24	152.25	37.79	34	135.24	33.35
AV-1	23	143.65	35.75	29	132.62	41.10
AV-3	19	131.05	31.86	25	133.00	35.77
AV-6	4	136.00	23.11	9	112.22	26.81
AV-1 – Baseline	22	-10.27	23.25	29	-2.62	29.46
AV-3 – Baseline	19	-17.58	30.37	25	-8.72	33.04
AV-6 – Baseline	4	-34.00	36.45	9	-27.67	33.90
HDL-C (mg/dl)						
Baseline	25	55.32	12.58	34	54.47	14.86
AV-1	23	59.17	13.34	29	55.31	15.06
AV-3	19	57.89	13.27	25	59.16	16.08
AV-6	4	64.75	14.22	9	52.00	12.36
AV-1 – Baseline	23	4.61	7.45	29	0.93	4.78
AV-3 – Baseline	19	3.63	10.58	25	6.36	8.03
AV-6 – Baseline	4	1.00	6.27	9	-0.22	8.64

(continues)

Table 2.8 (continued)
Blood Specimen Analysis: Unknown Race/Ethnicity

Data as of: February 29, 2004

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
HDL-2 (mg/dl)						
Baseline	25	16.48	6.76	33	16.03	8.12
AV-1	22	18.73	7.25	29	17.00	9.21
AV-3	19	16.42	6.27	25	17.08	6.24
AV-6	4	18.25	4.92	9	13.00	4.33
AV-1 – Baseline	22	1.91	5.08	28	0.57	4.14
AV-3 – Baseline	19	0.47	5.83	24	1.54	5.44
AV-6 – Baseline	4	-1.25	2.50	9	-1.22	6.51
HDL-3 (mg/dl)						
Baseline	25	38.84	7.11	33	38.00	7.80
AV-1	22	41.50	6.84	29	38.31	7.28
AV-3	19	41.47	7.76	25	42.08	10.74
AV-6	4	46.50	10.47	9	39.00	8.73
AV-1 – Baseline	22	3.00	4.86	28	0.18	3.38
AV-3 – Baseline	19	3.16	6.78	24	4.79	5.88
AV-6 – Baseline	4	2.25	5.12	9	1.00	3.50
Lp(a) (mg/dl)						
Baseline	25	20.64	22.31	34	27.41	25.20
AV-1	22	20.23	23.22	29	23.00	19.88
AV-3	18	15.28	12.95	23	26.13	21.89
AV-6	4	43.00	39.00	9	23.22	19.70
AV-1 – Baseline	22	-0.55	3.20	29	-3.55	15.82
AV-3 – Baseline	18	-1.67	3.83	23	-4.57	12.73
AV-6 – Baseline	4	-2.50	7.14	9	-6.78	22.32

Table 2.9
Bone Mineral Density[1] Analysis: HRT Participants

Data as of: February 29, 2004[2]

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan						
Baseline	938	1.01	0.11	1025	0.99	0.10
AV1	843	1.01	0.11	928	1.00	0.10
AV3	775	1.03	0.12	857	1.02	0.10
AV6	684	1.04	0.12	736	1.02	0.11
AV9	130	1.02	0.12	163	1.03	0.12
AV1 % Change from baseline BMD[3]	841	0.44	2.81	925	0.26	2.35
AV3 % Change from baseline BMD[3]	773	2.17	4.41	852	1.99	3.81
AV6 % Change from baseline BMD[3]	681	2.59	5.78	731	2.56	5.40
AV9 % Change from baseline BMD[3]	127	2.37	6.06	156	3.20	6.97
Spine Scan						
Baseline	907	0.97	0.16	991	0.95	0.16
AV1	818	0.99	0.16	893	0.97	0.16
AV3	758	1.00	0.17	833	0.99	0.17
AV6	654	1.01	0.17	715	0.99	0.17
AV9	125	0.98	0.17	155	0.98	0.17
AV1 % Change from baseline BMD[3]	815	1.90	4.57	891	2.08	4.34
AV3 % Change from baseline BMD[3]	755	3.51	6.19	829	4.10	6.04
AV6 % Change from baseline BMD[3]	650	4.41	7.62	711	4.83	7.56
AV9 % Change from baseline BMD[3]	121	4.27	9.39	149	5.49	8.44
Hip Scan						
Baseline	934	0.86	0.14	1024	0.84	0.13
AV1	841	0.86	0.14	928	0.84	0.13
AV3	775	0.88	0.15	860	0.86	0.14
AV6	683	0.87	0.14	747	0.84	0.13
AV9	128	0.83	0.14	164	0.83	0.13
AV1 % Change from baseline BMD[3]	838	0.71	3.31	925	0.64	3.17
AV3 % Change from baseline BMD[3]	769	2.19	4.83	854	2.16	4.77
AV6 % Change from baseline BMD[3]	677	0.18	5.89	735	0.59	5.77
AV9 % Change from baseline BMD[3]	125	-1.24	6.87	155	-1.20	6.83

[1] Measured in (g/cm^2).
[2] Because of technical problems, data from Birmingham are based on scans collected through October 2003 only.
[3] AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x100.

Table 2.10
Bone Mineral Density[1] Analysis: HRT Participants by Race/Ethnicity

Data as of: February 29, 2004[2]

	Black/African American						Hispanic/Latino						White					
	Without Uterus			With Uterus			Without Uterus			With Uterus			Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan																		
Baseline	174	1.06	0.10	99	1.08	0.11	66	1.03	0.10	61	1.02	0.11	686	0.99	0.10	843	0.98	0.09
AV1	153	1.07	0.11	86	1.08	0.11	44	1.04	0.10	50	1.03	0.10	635	1.00	0.10	775	0.99	0.09
AV3	150	1.09	0.11	87	1.10	0.12	51	1.05	0.12	45	1.06	0.11	566	1.01	0.12	708	1.00	0.10
AV6	130	1.08	0.11	68	1.08	0.12	48	1.09	0.11	43	1.09	0.14	498	1.02	0.12	610	1.01	0.11
AV9	14	1.08	0.09	8	1.13	0.10	11	1.08	0.15	7	1.19	0.23	105	1.00	0.12	145	1.02	0.10
AV1 % Change from baseline BMD[3]	153	0.75	2.95	86	0.91	2.86	44	-0.16	2.30	49	-0.07	2.42	633	0.40	2.80	773	0.21	2.27
AV3 % Change from baseline BMD[3]	150	2.06	3.45	87	2.15	3.18	51	1.66	4.58	44	3.15	5.43	564	2.24	4.63	704	1.88	3.77
AV6 % Change from baseline BMD[3]	130	0.61	4.01	68	0.44	4.05	48	5.79	6.55	42	5.87	6.53	495	2.80	5.92	606	2.57	5.38
AV9 % Change from baseline BMD[3]	12	-1.55	4.47	8	-0.11	3.79	11	7.32	7.03	7	10.81	6.67	104	2.29	5.80	138	3.03	6.95
Spine Scan																		
Baseline	171	1.04	0.15	98	1.08	0.19	65	0.96	0.13	59	0.92	0.13	659	0.95	0.16	812	0.93	0.15
AV1	150	1.05	0.16	85	1.09	0.19	44	0.97	0.11	47	0.94	0.14	613	0.97	0.16	744	0.96	0.16
AV3	147	1.07	0.17	86	1.11	0.20	51	0.95	0.13	43	0.95	0.14	552	0.99	0.17	687	0.97	0.16
AV6	116	1.08	0.17	66	1.08	0.19	48	0.98	0.14	40	0.93	0.15	482	1.00	0.17	594	0.98	0.17
AV9	14	1.06	0.18	8	1.23	0.26	11	0.94	0.15	5	0.96	0.14	100	0.97	0.16	139	0.97	0.15
AV1 % Change from baseline BMD[3]	150	1.92	4.39	85	1.74	4.81	44	-0.70	4.46	47	1.74	6.95	610	2.11	4.56	742	2.14	4.09
AV3 % Change from baseline BMD[3]	147	3.43	6.16	86	2.92	6.37	51	-0.35	5.62	43	3.14	6.89	549	3.91	6.11	683	4.31	5.93
AV6 % Change from baseline BMD[3]	116	3.31	6.92	66	2.29	7.16	48	1.84	6.68	40	2.81	8.85	478	5.01	7.81	590	5.20	7.46
AV9 % Change from baseline BMD[3]	12	-0.69	6.69	8	1.22	8.61	11	4.60	7.65	5	5.24	10.53	98	4.84	9.72	133	5.78	8.44
Hip Scan																		
Baseline	174	0.96	0.13	98	0.97	0.15	65	0.87	0.11	61	0.84	0.13	683	0.83	0.13	843	0.82	0.12
AV1	153	0.97	0.13	86	0.97	0.14	43	0.87	0.11	50	0.85	0.12	634	0.83	0.13	775	0.83	0.12
AV3	150	0.98	0.14	87	0.99	0.15	50	0.89	0.13	45	0.88	0.13	567	0.85	0.14	711	0.84	0.13
AV6	131	0.95	0.13	69	0.94	0.14	47	0.89	0.13	43	0.86	0.11	497	0.84	0.13	620	0.83	0.12
AV9	14	0.94	0.15	8	0.96	0.14	11	0.83	0.18	7	0.84	0.16	103	0.81	0.14	146	0.82	0.12
AV1 % Change from baseline BMD[3]	153	1.14	2.96	86	1.12	3.46	43	0.31	3.62	49	1.06	3.48	631	0.64	3.38	773	0.56	3.13
AV3 % Change from baseline BMD[3]	150	1.85	3.89	87	1.36	3.94	50	2.76	5.28	44	4.57	6.04	561	2.23	5.00	706	2.07	4.75
AV6 % Change from baseline BMD[3]	131	-1.55	5.35	68	-2.44	5.11	47	2.44	6.02	42	4.15	6.47	491	0.47	5.91	610	0.67	5.67
AV9 % Change from baseline BMD[3]	12	-3.34	7.23	8	-4.05	6.90	11	2.51	8.06	7	1.73	7.12	102	-1.40	6.62	138	-1.17	6.83

[1] Measured in (g/cm2).
[2] Because of technical problems, data from Birmingham are based on scans collected through October 2003 only.
[3] AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x100.

Table 2.11
Lost-to-Follow-up and Vital Status: HRT Participants by Hysterectomy Status

Data as of: February 29, 2004

	Without Uterus (N=10,739)		With Uterus (N=16,608)		HRT Participants (N=27,347)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	580	5.4	714	4.3	1294	4.7
Alive: Current Participation[1]	9450	88.0	15030	90.5	24480	89.5
Alive: Recent Participation[2]	146	1.4	229	1.4	375	1.4
Alive: Past/Unknown Participation[3]	7	0.1	4	0.0	11	0.0
Stopped Follow-Up[4]	321	3.0	438	2.6	759	2.8
Lost to Follow-Up[5]	235	2.2	193	1.2	428	1.6

[1] Participants who have filled in a Form 33 within the last 9 months.
[2] Participants who last filled in a Form 33 between 9 and 18 months ago.
[3] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 2.12
Verified Outcomes (Annualized Percentages) by Age for Hormone Replacement Therapy

Data as of: February 29, 2004

Outcomes	Total	Age 50-54	Age 55-59	Age 60-69	Age 70-79
Number randomized	27347	3421	5410	12364	6152
Mean follow-up (months)	82.3	87.7	84.7	81.4	78.9
Cardiovascular					
CHD[1]	808 (0.43%)	41 (0.16%)	81 (0.21%)	369 (0.44%)	317 (0.78%)
CHD death[2]	215 (0.11%)	8 (0.03%)	19 (0.05%)	85 (0.10%)	103 (0.25%)
Total MI[3]	660 (0.35%)	35 (0.14%)	66 (0.17%)	304 (0.36%)	255 (0.63%)
Clinical MI	629 (0.34%)	34 (0.14%)	64 (0.17%)	288 (0.34%)	243 (0.60%)
Evolving Q-wave MI[4]	31 (0.02%)	1 (<0.01%)	2 (0.01%)	16 (0.02%)	12 (0.03%)
Possible evolving Q-wave MI[4]	145 (0.08%)	15 (0.06%)	19 (0.05%)	57 (0.07%)	54 (0.13%)
Angina	944 (0.50%)	41 (0.16%)	119 (0.31%)	457 (0.55%)	327 (0.81%)
CABG/PTCA	1013 (0.54%)	43 (0.17%)	119 (0.31%)	497 (0.59%)	354 (0.87%)
Carotid artery disease	186 (0.10%)	4 (0.02%)	17 (0.04%)	101 (0.12%)	64 (0.16%)
Congestive heart failure	630 (0.34%)	32 (0.13%)	65 (0.17%)	257 (0.31%)	276 (0.68%)
Stroke	612 (0.33%)	22 (0.09%)	61 (0.16%)	270 (0.32%)	259 (0.64%)
Non-disabling stroke	326 (0.17%)	18 (0.07%)	38 (0.10%)	137 (0.16%)	133 (0.33%)
Fatal/disabling stroke	197 (0.11%)	2 (0.01%)	15 (0.04%)	85 (0.10%)	95 (0.23%)
Unknown status from stroke	89 (0.05%)	2 (0.01%)	8 (0.02%)	48 (0.06%)	31 (0.08%)
PVD	174 (0.09%)	7 (0.03%)	16 (0.04%)	86 (0.10%)	65 (0.16%)
DVT	346 (0.18%)	18 (0.07%)	46 (0.12%)	159 (0.19%)	123 (0.30%)
Pulmonary embolism	236 (0.13%)	16 (0.06%)	31 (0.08%)	116 (0.14%)	73 (0.18%)
CHD[1]/Possible evolving Q-wave MI	944 (0.50%)	56 (0.22%)	100 (0.26%)	423 (0.50%)	365 (0.90%)
Coronary disease[5]	2231 (1.19%)	116 (0.46%)	259 (0.68%)	1038 (1.24%)	818 (2.02%)
DVT/PE	466 (0.25%)	25 (0.10%)	61 (0.16%)	225 (0.27%)	155 (0.38%)
Total cardiovascular disease	3320 (1.77%)	165 (0.66%)	382 (1.00%)	1558 (1.86%)	1215 (3.00%)
Cancer					
Breast cancer	801 (0.43%)	77 (0.31%)	146 (0.38%)	381 (0.45%)	197 (0.49%)
Invasive breast cancer	640 (0.34%)	57 (0.23%)	121 (0.32%)	296 (0.35%)	166 (0.41%)
Non-invasive breast cancer	165 (0.09%)	20 (0.08%)	26 (0.07%)	88 (0.10%)	31 (0.08%)
Ovarian cancer	64 (0.03%)	2 (0.01%)	12 (0.03%)	34 (0.04%)	16 (0.04%)
Endometrial cancer[6]	70 (0.04%)	3 (0.01%)	16 (0.04%)	36 (0.04%)	15 (0.04%)
Colorectal cancer	274 (0.15%)	17 (0.07%)	25 (0.07%)	142 (0.17%)	90 (0.22%)
Other cancer[7]	1032 (0.55%)	75 (0.30%)	147 (0.39%)	476 (0.57%)	334 (0.83%)
Total cancer	2160 (1.15%)	171 (0.68%)	336 (0.88%)	1026 (1.22%)	627 (1.55%)
Fractures					
Hip fracture	285 (0.15%)	3 (0.01%)	13 (0.03%)	87 (0.10%)	182 (0.45%)
Vertebral fracture	273 (0.15%)	7 (0.03%)	29 (0.08%)	110 (0.13%)	127 (0.31%)
Other fracture[7]	2805 (1.50%)	317 (1.27%)	448 (1.17%)	1305 (1.56%)	735 (1.82%)
Total fracture	3207 (1.71%)	325 (1.30%)	479 (1.26%)	1443 (1.72%)	960 (2.37%)
Deaths					
Cardiovascular deaths	388 (0.21%)	12 (0.05%)	31 (0.08%)	153 (0.18%)	192 (0.47%)
Cancer deaths	555 (0.30%)	26 (0.10%)	65 (0.17%)	263 (0.31%)	201 (0.50%)
Other known cause	228 (0.12%)	13 (0.05%)	31 (0.08%)	89 (0.11%)	95 (0.23%)
Unknown cause	60 (0.03%)	4 (0.02%)	8 (0.02%)	26 (0.03%)	22 (0.05%)
Not yet adjudicated	63 (0.03%)	6 (0.02%)	6 (0.02%)	24 (0.03%)	27 (0.07%)
Total death	1294 (0.69%)	61 (0.24%)	141 (0.37%)	555 (0.66%)	537 (1.33%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI' includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 2.12 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Hormone Replacement Therapy

Data as of: February 29, 2004

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	130	527	2738	1537	22030	385
Mean follow-up (months)	80.2	78.0	81.6	79.4	82.7	78.2
Cardiovascular						
CHD[1]	5 (0.58%)	9 (0.26%)	88 (0.47%)	23 (0.23%)	666 (0.44%)	17 (0.68%)
CHD death[2]	2 (0.23%)	4 (0.12%)	40 (0.21%)	4 (0.04%)	162 (0.11%)	3 (0.12%)
Total MI[3]	4 (0.46%)	8 (0.23%)	59 (0.32%)	19 (0.19%)	555 (0.37%)	15 (0.60%)
Clinical MI	4 (0.46%)	7 (0.20%)	58 (0.31%)	19 (0.19%)	527 (0.35%)	14 (0.56%)
Evolving Q-wave MI[4]	0 (0.00%)	1 (0.03%)	1 (0.01%)	0 (0.00%)	28 (0.02%)	1 (0.04%)
Possible evolving Q-wave MI[4]	0 (0.00%)	2 (0.06%)	14 (0.08%)	8 (0.08%)	120 (0.08%)	1 (0.04%)
Angina	6 (0.69%)	15 (0.44%)	107 (0.57%)	37 (0.36%)	770 (0.51%)	9 (0.36%)
CABG/PTCA	7 (0.81%)	10 (0.29%)	90 (0.48%)	37 (0.36%)	856 (0.56%)	13 (0.52%)
Carotid artery disease	1 (0.12%)	1 (0.03%)	7 (0.04%)	1 (0.01%)	174 (0.11%)	2 (0.08%)
Congestive heart failure	3 (0.35%)	7 (0.20%)	82 (0.44%)	21 (0.21%)	511 (0.34%)	6 (0.24%)
Stroke	5 (0.58%)	12 (0.35%)	86 (0.46%)	20 (0.20%)	478 (0.31%)	11 (0.44%)
Non-disabling stroke	3 (0.35%)	7 (0.20%)	37 (0.20%)	12 (0.12%)	262 (0.17%)	5 (0.20%)
Fatal/disabling stroke	2 (0.23%)	4 (0.12%)	31 (0.17%)	4 (0.04%)	152 (0.10%)	4 (0.16%)
Unknown status from stroke	0 (0.00%)	1 (0.03%)	18 (0.10%)	4 (0.04%)	64 (0.04%)	2 (0.08%)
PVD	2 (0.23%)	1 (0.03%)	17 (0.09%)	2 (0.02%)	152 (0.10%)	0 (0.00%)
DVT	1 (0.12%)	1 (0.03%)	32 (0.17%)	4 (0.04%)	307 (0.20%)	1 (0.04%)
Pulmonary embolism	3 (0.35%)	1 (0.03%)	26 (0.14%)	3 (0.03%)	201 (0.13%)	2 (0.08%)
CHD[1]/Possible evolving Q-wave MI	5 (0.58%)	11 (0.32%)	101 (0.54%)	31 (0.30%)	778 (0.51%)	18 (0.72%)
Coronary disease[5]	11 (1.27%)	28 (0.82%)	254 (1.36%)	80 (0.79%)	1829 (1.20%)	29 (1.16%)
DVT/PE	4 (0.46%)	1 (0.03%)	45 (0.24%)	6 (0.06%)	408 (0.27%)	2 (0.08%)
Total cardiovascular disease	18 (2.07%)	40 (1.17%)	368 (1.98%)	106 (1.04%)	2748 (1.81%)	40 (1.59%)
Cancer						
Breast cancer	3 (0.35%)	20 (0.58%)	69 (0.37%)	27 (0.27%)	676 (0.45%)	6 (0.24%)
Invasive breast cancer	3 (0.35%)	15 (0.44%)	54 (0.29%)	20 (0.20%)	542 (0.36%)	6 (0.24%)
Non-invasive breast cancer	0 (0.00%)	5 (0.15%)	15 (0.08%)	7 (0.07%)	138 (0.09%)	0 (0.00%)
Ovarian cancer	0 (0.00%)	0 (0.00%)	5 (0.03%)	0 (0.00%)	58 (0.04%)	1 (0.04%)
Endometrial cancer[6]	1 (0.12%)	0 (0.00%)	2 (0.01%)	3 (0.03%)	64 (0.04%)	0 (0.00%)
Colorectal cancer	1 (0.12%)	7 (0.20%)	25 (0.13%)	13 (0.13%)	223 (0.15%)	5 (0.20%)
Other cancer[7]	6 (0.69%)	16 (0.47%)	83 (0.45%)	32 (0.31%)	882 (0.58%)	13 (0.52%)
Total cancer	11 (1.27%)	43 (1.25%)	175 (0.94%)	71 (0.70%)	1836 (1.21%)	24 (0.96%)
Fractures						
Hip fracture	0 (0.00%)	3 (0.09%)	8 (0.04%)	5 (0.05%)	267 (0.18%)	2 (0.08%)
Vertebral fracture	2 (0.23%)	2 (0.06%)	3 (0.02%)	3 (0.03%)	260 (0.17%)	3 (0.12%)
Other fracture[7]	12 (1.38%)	37 (1.08%)	152 (0.82%)	96 (0.94%)	2478 (1.63%)	30 (1.20%)
Total fracture	13 (1.50%)	41 (1.20%)	162 (0.87%)	100 (0.98%)	2858 (1.88%)	33 (1.32%)
Deaths						
Cardiovascular deaths	3 (0.35%)	7 (0.20%)	70 (0.38%)	5 (0.05%)	299 (0.20%)	4 (0.16%)
Cancer deaths	3 (0.35%)	12 (0.35%)	49 (0.26%)	18 (0.18%)	467 (0.31%)	6 (0.24%)
Other known cause	4 (0.46%)	2 (0.06%)	24 (0.13%)	2 (0.02%)	196 (0.13%)	0 (0.00%)
Unknown cause	0 (0.00%)	1 (0.03%)	10 (0.05%)	3 (0.03%)	42 (0.03%)	4 (0.16%)
Not yet adjudicated	0 (0.00%)	0 (0.00%)	8 (0.04%)	4 (0.04%)	51 (0.03%)	0 (0.00%)
Total Death	10 (1.15%)	22 (0.64%)	161 (0.86%)	32 (0.31%)	1055 (0.69%)	14 (0.56%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 2.13
Verified Outcomes (Annualized Percentages) for HRT Participants Without and With Uterus

Data as of: February 29, 2004

Outcomes	Without Uterus		With Uterus	
Number randomized	10739		16608	
Mean follow-up (months)	81.8		82.6	
Cardiovascular				
CHD[1]	376	(0.51%)	432	(0.38%)
CHD death[2]	113	(0.15%)	102	(0.09%)
Total MI[3]	301	(0.41%)	359	(0.31%)
Clinical MI	287	(0.39%)	342	(0.30%)
Evolving Q-wave MI[4]	14	(0.02%)	17	(0.01%)
Possible evolving Q-wave MI[4]	52	(0.07%)	93	(0.08%)
Angina	501	(0.68%)	443	(0.39%)
CABG/PTCA	485	(0.66%)	528	(0.46%)
Carotid artery disease	96	(0.13%)	90	(0.08%)
Congestive heart failure	332	(0.45%)	298	(0.26%)
Stroke	276	(0.38%)	336	(0.29%)
Non-disabling stroke	141	(0.19%)	185	(0.16%)
Fatal/disabling stroke	87	(0.12%)	110	(0.10%)
Unknown status from stroke	48	(0.07%)	41	(0.04%)
PVD	83	(0.11%)	91	(0.08%)
DVT	131	(0.18%)	215	(0.19%)
Pulmonary embolism	85	(0.12%)	151	(0.13%)
CHD[1]/Possible evolving Q-wave MI	426	(0.58%)	518	(0.45%)
Coronary disease[5]	1088	(1.49%)	1143	(1.00%)
DVT/PE	179	(0.24%)	287	(0.25%)
Total cardiovascular disease	1557	(2.13%)	1763	(1.54%)
Cancer				
Breast cancer	268	(0.37%)	533	(0.47%)
Invasive breast cancer	218	(0.30%)	422	(0.37%)
Non-invasive breast cancer	51	(0.07%)	114	(0.10%)
Ovarian cancer	17	(0.02%)	47	(0.04%)
Endometrial cancer[6]	0	N/A	70	(0.06%)
Colorectal cancer	119	(0.16%)	155	(0.14%)
Other cancer[7]	399	(0.55%)	633	(0.55%)
Total cancer	780	(1.07%)	1380	(1.21%)
Fractures				
Hip fracture	102	(0.14%)	183	(0.16%)
Vertebral fracture	103	(0.14%)	170	(0.15%)
Other fracture[7]	1079	(1.47%)	1726	(1.51%)
Total fracture	1227	(1.68%)	1980	(1.73%)
Deaths				
Cardiovascular deaths	188	(0.26%)	200	(0.18%)
Cancer deaths	240	(0.33%)	315	(0.28%)
Other known cause	89	(0.12%)	139	(0.12%)
Unknown cause	33	(0.05%)	27	(0.02%)
Not yet adjudicated	30	(0.04%)	33	(0.03%)
Total death	580	(0.79%)	714	(0.62%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 2.14
Frequency (%)[1] of Various Subcategories of Stroke Diagnosis: HRT Participants

Data as of: February 29, 2004

	Without Uterus		With Uterus	
Number randomized	10739		16608	
Stroke Diagnosis				
Subarachoid hemorrhage	12	4.3%	11	3.3%
Intracerebral hemorrhage	25	9.1%	35	10.4%
Other intracranial hemorrhage	1	0.4%	3	0.9%
Occlusion of cerebral arteries with infarction	205	74.3%	248	73.8%
Acute cerebrovascular disease	2	0.7%	1	0.3%
Report of cerebrovascular death only	10	3.6%	17	5.1%
Missing/not centrally confirmed	21	7.6%	21	6.3%
Total	276	100%	336	100%

[1] Percentages are relative to the total number of stroke diagnoses.

Table 2.15
Frequency (%)[1] of Disability Levels Following Stroke – Glasgow Scale: HRT Participants

Data as of: February 29, 2004

	Without Uterus		With Uterus	
Number randomized	10739		16608	
Glasgow scale				
Good recovery	74	26.8%	88	26.2%
Moderately disabled	67	24.3%	97	28.9%
Severely disabled	57	20.7%	65	19.3%
Vegetative survival	1	0.4%	3	0.9%
Death or death within 1 month	29	10.5%	42	12.5%
Unable to categorize stroke	28	10.1%	19	5.7%
Not yet categorized	20	7.2%	22	6.5%
Total	276	100%	336	100%

[1] Percentages are relative to the total number of stroke diagnoses.

Table 2.16
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for HRT Participants who did not report a prevalent condition at baseline

Data as of: February 29, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	27347	3421	5410	12364	6152
Mean follow-up (months)	82.3	87.7	84.7	81.4	78.9
Hospitalizations					
Ever	12688 (6.77%)	1126 (4.51%)	2009 (5.26%)	5897 (7.03%)	3656 (9.04%)
Two or more	6800 (3.63%)	527 (2.11%)	953 (2.50%)	3142 (3.75%)	2178 (5.38%)
Other					
Diabetes (treated)	1979 (1.12%)	269 (1.12%)	387 (1.07%)	918 (1.16%)	405 (1.06%)
Gallbladder disease[1]	1877 (1.20%)	252 (1.17%)	394 (1.21%)	872 (1.26%)	359 (1.09%)
Hysterectomy	610 (0.53%)	55 (0.37%)	113 (0.46%)	303 (0.59%)	139 (0.59%)
Glaucoma	2739 (1.53%)	238 (0.97%)	462 (1.24%)	1308 (1.63%)	731 (1.95%)
Osteoporosis	5372 (3.02%)	406 (1.65%)	815 (2.20%)	2596 (3.27%)	1555 (4.26%)
Osteoarthritis[2]	4334 (3.73%)	543 (2.87%)	865 (3.26%)	1983 (3.95%)	943 (4.58%)
Rheumatoid arthritis	1464 (0.82%)	181 (0.75%)	310 (0.84%)	655 (0.82%)	318 (0.83%)
Intestinal polyps	3467 (1.99%)	354 (1.46%)	610 (1.67%)	1765 (2.26%)	738 (2.06%)
Lupus	255 (0.14%)	33 (0.13%)	52 (0.14%)	116 (0.14%)	54 (0.13%)
Kidney stones[2]	638 (0.41%)	76 (0.38%)	121 (0.38%)	288 (0.41%)	153 (0.45%)
Cataracts[2]	7606 (5.51%)	405 (2.00%)	1100 (3.52%)	4085 (6.48%)	2016 (8.60%)
Pills for hypertension	6597 (4.96%)	733 (3.64%)	1247 (4.23%)	3031 (5.22%)	1586 (6.25%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	130	527	2738	1537	22030	385
Mean follow-up (months)	80.2	78.0	81.6	79.4	82.7	78.2
Hospitalizations						
Ever	65 (7.48%)	168 (4.90%)	1318 (7.08%)	566 (5.56%)	10401 (6.85%)	170 (6.78%)
Two or more	40 (4.60%)	79 (2.31%)	725 (3.90%)	252 (2.48%)	5618 (3.70%)	86 (3.43%)
Other						
Diabetes (treated)	12 (1.60%)	44 (1.40%)	323 (1.98%)	175 (1.87%)	1396 (0.96%)	29 (1.25%)
Gallbladder disease[1]	12 (1.82%)	27 (0.87%)	160 (0.96%)	107 (1.40%)	1545 (1.23%)	26 (1.26%)
Hysterectomy	2 (0.55%)	5 (0.21%)	37 (0.48%)	29 (0.50%)	531 (0.55%)	6 (0.39%)
Glaucoma	15 (1.84%)	53 (1.61%)	349 (2.03%)	160 (1.63%)	2123 (1.45%)	39 (1.67%)
Osteoporosis	27 (3.29%)	121 (3.67%)	278 (1.55%)	285 (3.01%)	4583 (3.19%)	78 (3.28%)
Osteoarthritis[2]	28 (4.78%)	92 (3.80%)	438 (3.89%)	311 (4.41%)	3394 (3.64%)	71 (4.39%)
Rheumatoid arthritis	9 (1.17%)	27 (0.82%)	238 (1.40%)	194 (2.01%)	972 (0.67%)	24 (1.01%)
Intestinal polyps	19 (2.37%)	54 (1.72%)	355 (2.04%)	174 (1.79%)	2831 (2.01%)	34 (1.47%)
Lupus	2 (0.23%)	4 (0.12%)	30 (0.16%)	18 (0.18%)	200 (0.13%)	1 (0.04%)
Kidney stones[2]	7 (1.03%)	21 (0.72%)	64 (0.41%)	48 (0.57%)	491 (0.39%)	7 (0.33%)
Cataracts[2]	37 (5.60%)	127 (4.98%)	697 (5.05%)	388 (4.77%)	6260 (5.64%)	97 (5.25%)
Pills for hypertension	40 (6.54%)	125 (5.21%)	608 (6.60%)	409 (5.36%)	5340 (4.79%)	75 (4.61%)

[1] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[2] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

3. DM Component

3.1 Recruitment

WHI randomized 48,835 women into the Dietary Modification component, 102% of goal. Age-specific DM recruitment data are presented in *Table 3.1 – Dietary Modification Component Age - Specific Recruitment.* The age fractions exceeded the design assumptions for ages 50-54, 55-59, and 60-69. For the age category 70-79, recruitment was lower than designed.

3.2 Adherence

Nutrient intake data for adherence monitoring are presented in *Table 3.2 – Nutrient Intake Monitoring* and *Figure 3.1 – Nutrient Intake.* Studywide, the Food Frequency Questionnaire (FFQ) mean difference between Intervention and Control women is 10.9% energy from fat at AV-1 decreasing to 7.9% at AV-8. This report presents nutrient intake comparisons for each racial/ethnic group separately (*Table 3.3*). Because of sparse data, some of these results are highly variable. The C-I value in minority women is roughly 1-3 percentage points lower compared to white women. All C-I analyses are based on only those women providing a food frequency questionnaire at the designated visit. Percent of missing FFQs has remained fairly constant over time: 7.9% missing at AV-1, 10.3% at AV-3, 11.4% at AV-5, and 12.1% at AV-8.

For fruit and vegetable intake, the mean difference between the arms of the trial remains consistently in excess of 1 more serving per day for Intervention vs. Control women. Compared to Control women, Intervention women consumed almost 1 more serving per day of grains at AV-1, decreasing to one-third serving at AV-9. Generally, the C-I for fruit and vegetables intake, as well as grain intake, are similar across race/ethnicity groups.

Multivariate analyses were conducted to identify factors associated with C-I differences in percent energy from fat based on FFQs collected in the past year and controlling for visit year and clinic effect (*Table 3.4 – Control – Intervention Difference in % Energy from Fat in WHI DM Participants Study Subject Characteristics and Session Participation from FFQs Collected in the Last Year*). Separate analyses were conducted to examine session attendance, completion, and fat score provision variables in relation to C-I because these measures are highly correlated. For example, self-monitoring scores are almost always provided at sessions, and therefore session attendance (and completion) is closely associated with self-monitoring. The participant characteristics that are consistently associated with a lower C-I difference are being Black compared to White ($p<0.01$), Hispanic compared to White ($p<0.01$), and age 70-79 years compared to 60-69 years at randomization ($p<0.01$ for the models including session attendance and fat score provision, $p<0.05$ for the model including session completion). The three intervention participation variables – Session attendance, completion, and self-monitoring – are all significantly associated with much higher (i.e., better) C-I values.

Body weight data are presented in *Figure 3.2 – Mean Body Weight for DM Participants Stratified by Treatment Arm.* Here we describe the paired differences in weight change from baseline. From baseline to AV-1, women in the intervention arm reduced body weight by an average of 2.2 kg in comparison to no change for women in the control arm. Although women in the intervention arm have gradually experienced a return to mean baseline weight by about AV-8, control women have gained weight over time and hence the difference between the arms of the trial is statistically

significant at every annual visit ($p<0.01$). From a trend perspective, these results are consistent with changes in energy intake estimated with the FFQ.

Tables 3.5 and *3.6 – Reasons for Stopping DM* give reasons for stopping DM Intervention activities categorized by general type and stratified by age and race/ethnicity. Overall, the major reasons for stopping given by participants were family responsibilities (10.1%), demands of work (8.5%), and issues of interest in the study (9.4%). Issues specifically related to the DM intervention were seldom mentioned. The age and race/ethnicity stratified analyses have sparse numbers and may be confounded by other factors, and therefore should be interpreted cautiously. These data suggest that older participants were less likely to indicate that they were stopping due the demands of work, but were also less likely to stop the DM intervention because it was "Too far to the CC." Compared to the other race/ethnicity groups, Hispanic/Latino women were the most likely to indicate that they were stopping intervention because of family demands, but the least likely to stop intervention because of lack of interest in the study. Black/African American women were the most likely to stop DM because of demands of work and/or issues of interest in the study.

3.3 Blood Specimen Analyses

Tables 3.7 and *Table 3.8 – Blood Specimen Analysis* presents blinded blood analyte data DM studywide and by race/ethnicity. Changes between AV-1 and Baseline, AV-3 and Baseline, and AV-6 and Baseline appeared for alpha-tocopherol (positive), gamma-tocopherol (negative), fibrinogen (negative), glucose (negative), triglyceride (positive), total cholesterol (negative), LDL-cholesterol (negative), and HDL-cholesterol (negative). The trends in lipids are similar to what is seen with isocaloric low-fat high carbohydrate diets. However, interpretations may only be surmised due to the blinded nature of the data. For the most part, similar trends occurred among the ethnic/racial groups. Data are just beginning to accrue for AV-6 and thus interpretation for that time period is particularly risky.

3.4 Bone Density Analyses

Tables 3.9 and *3.10 – Bone Mineral Density Analysis* present blinded bone mineral density data from the DM bone density subsample overall and by race/ethnicity. Changes from baseline to AV-1, AV-3, and AV-6 occurred with increases in mean bone mineral density in the whole body scan as well as the spine and hip scan. Data are beginning to accrue for AV-9, but are too sparse for interpretation. There were, generally, similar trends by race/ethnicity. An increase in BMD is not expected from this intervention. Possible reasons for these increases include use of calcium supplements and/or HRT, selection of health-conscious women, incomplete BMD data (e.g., 12.6% missing at AV-3), or measurement issues.

3.5 Vital Status

Table 3.11 – Lost-to-Follow-up and Vital Status: DM Participants presents data on the vital status and the participation status of participants in the DM trial. A detailed description of CCC and clinic activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes Processing*. For operational purposes, we define CT participants to have an "unknown" participation status if there is no outcomes information from the participant for 18 months and no other contacts for 6 months. Currently, about 3.9% of the DM participants are lost-to-follow-up or have stopped follow-up, and 3.8% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in

the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or death. Currently, the average follow-up for DM participants is about 7.1 years, suggesting that approximately 19.4% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

3.6 Outcomes

Table 3.12 – Verified Outcomes (Annualized Percentages) by Age and Race/Ethnicity for Dietary Modification contains counts of the number of verified major WHI outcomes for DM participants by race/ethnicity and age. We are reporting centrally adjudicated outcomes for those outcomes that are centrally adjudicated for all participants in a component. Thus, for the DM component we are using centrally adjudicated outcomes for breast cancer, ovarian cancer, endometrial cancer, colorectal cancer, hip fractures, and death. Locally verified outcomes for events for which central adjudication has not yet been completed are included in the counts. Approximately 3% of the self-reported outcomes have not yet been verified, so the numbers in this table can be seen as a lower bound to the actual number of outcomes that have occurred. Compared to the design assumptions, we have observed almost 115% of the expected number of breast cancers, 70% of the expected number of colorectal cancers, about 65% of the expected number of CHD events, and about 35% of the expected number hip fractures.

Table 3.13 – Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for DM Participants contains counts of the number of self-reports for some outcomes that are not verified in WHI. As most of the locally verified outcomes are somewhat over reported (see *Section 6.3 – Outcomes Data Quality)*, the number in this table should be taken as an upper bound to the number of events that have occurred in DM participants.

3.7 Issues

As noted above, the C-I percent energy from fat difference is less than the design assumptions. The WHI investigators and staff have undertaken regular, annual initiatives to improve adherence.

In 2000, the DM Intervention incorporated an Intensive Intervention Program (IIP) that consisted of a series of three interviews using motivational enhancement counseling techniques. A preliminary evaluation of the IIP among intervention participants indicated that when examining change (increases) in fat intake from AV-1 to most recent data collection, participants who received IIP contact had an increase in fat intake that was 0.75 percentage points less (i.e., had less slippage) than intervention women who did not receive IIP ($p<0.05$).

In 2001, we conducted a Targeted Message Campaign. Participants received a mailing designed to help them rediscover their intrinsic motivation(s) for participating in WHI, which was followed by a supportive motivational enhancement call. Based on information collected on the call, a second targeted mailing allowed a woman to select an action consistent with her readiness to enhance her intervention adherence.

In 2002, a Dietary Modification Working Group developed a third initiative called the Personalized Evaluation of Fat Intake (PEFI). This intervention uses tailored, food-based, feedback to facilitate dietary goal re-setting for participants. The dietary assessment was performed using a questionnaire on usual fat-intake over the past 4 weeks. After scanning,

computerized algorithms provide printed, individualized feedback on estimated grams of fat consumed (overall and by foods) and food-specific behavioral change suggestions. The dietary questionnaire was administered during summer sessions and the written feedback was provided and reinforced in fall sessions. Overall, 74.6% of WHI intervention participants completed this protocol and the top five sources of fat were peanuts and other nuts; popcorn made with oil; beef, pork, lamb; peanut butter; and cheese.

In 2003, we conducted a centralized "self-help" PEFI protocol that provided women the opportunity to participate in a second round of assessment and feedback. The CCC mailed PEFI questionnaires to participants, scanned returned forms, printed the tailored feedback, and mailed the printed feedback with interpretation guide to the participants. Clinics had the option to provide this self-help PEFI locally, which a few did. This initiative began in September 2003 and ended in March 2004. The response rate was 64%, quite close to the 70% we expected based on this first self-help-based augmented intervention. We have not yet analyzed the data relative to fat intake.

Providing ongoing behavioral support of nutritionists remains a priority. In Summer 2003 and Spring 2004, the CCC led a series of dietary behavioral-focused conference calls with CC nutritionists, which were co-lead by the CCC behaviorist and a CCC nutritionist. The intent of the calls was to support CC nutritionists in their motivational enhancement, group facilitation, or other behavioral approaches. During 2003, the focus was adherence and during 2004, it was close-out of the dietary intervention. Note that a similar series of calls were conducted in 1999, 2000, and 2001; and were well attended and very positively rated by CC nutritionists.

The focus of DM materials development is shifting from intervention to close-out. Through collaborative efforts of the Dietary Modification Committee and subgroup, the Close-out Working Group, and in large part the Clinical Center and Coordinating Center nutritionists, several close-out materials are being developed. The entire last year of intervention sessions has been gradually leading DM intervention participants to the final session by providing summary and celebratory activities. For the close-out visit, DM participants (intervention and comparison) will receive two DM-specific handouts, a Dietary Summary outlining the WHI dietary goals in comparison to national guidelines to provide context for the WHI DM study goals without implying recommendations, and a set of frequently asked questions about the ending of the DM intervention-based study. In addition to DM-specific handouts, participants will receive general materials at their close-out visit.

3.8. Nutritional Biomarkers Substudy (NBS), a Substudy within the WHI DM

In late 2003, the DM Committee proposed conducting a study of nutritional biomarkers in a subset of DM study participants. Shortly thereafter, in January 2004, the WHI Steering Committee voted to approve the WHI Nutritional Biomarkers Substudy (NBS), to be funded from within the WHI CCC contract through monies that have been reserved for explanatory analyses in the DM trial. The principal aim of the NBS is to collect biomarkers of energy expenditure and nutrient intake in 550 DM participants (275 intervention and 275 control). The biomarker data will be used to calibrate the dietary assessment (FFQ) measurements, thus refining our ability to interpret the DM results in relation to dietary intake. The principal biomarkers being collected are doubly labeled water (DLW) measures of energy expenditure and urinary nitrogen (UN) estimates of protein intake. In addition to energy and protein measures, plasma phospholipids fatty acids and

biomarkers of micronutrient intake will be collected, e.g., blood tocopherols, retinol, folate, carotenoids, B-vitamins, selenium, and urinary potassium and sodium.

Operationally, 12 WHI CCs have been selected to participate in the NBS based on their interest, experience with nutrition studies involving biological specimen protocols and dietary assessment, investigator involvement with the DM study, and WHI DM performance. The participating CCs will recruit participants according to substrata matching WHI's age and race/ethnicity distribution. Ten of the CCs will each recruit 50 women, half DM-intervention and half DM-control. Two CCs will each recruit only minority participants, 25 (and up to 50) participants each. Interested, eligible, and consenting DM participants will complete a 2-visit protocol between May and September 2004 (in conjunction with their annual clinic visit) involving ingestion of doubly labeled water and follow-up measurement of urinary isotope output (for energy expenditure), one 24-hour urine collection (for UN and protein intake, and urinary sodium and potassium), a fasting blood draw (for micronutrient analysis), completion of an FFQ, vitamin/mineral supplement use interview, self-report of physical activity, and measurement of height and weight. A 20% reliability subsample (110 participants) will repeat the entire protocol approximately 6 months after their initial participation (between October 2004 and March 2005 during the WHI close-out window) and will also complete two 24-hour recalls. There is the potential for some CCs to add indirect calorimetry to the protocol by working with their local General Clinical Research Centers.

A copy of the NBS protocol is available, upon request.

Table 3.1
Dietary Modification Component Age – and Race/Ethnicity – Specific Recruitment

Data as of: February 29, 2004

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**48,835**			
50-54	6,961	149%	14%	10%
55-59	11,039	118%	23%	20%
60-69	22,715	108%	47%	45%
70-79	8,120	70%	17%	25%
Race/Ethnicity	**48,835**			
American Indian	202		<1%	
Asian	1,105		2%	
Black	5,262		11%	
Hispanic	1,845		4%	
White	39,762		81%	
Unknown	659		1%	

Table 3.2
Nutrient Intake Monitoring

Data as of: February 29, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	19541	38.8	5.0	29294	38.8	5.0	0.0	0.0	0.83
FFQ Year 1[3]	18099	25.2	7.5	26776	36.1	6.9	10.9	0.1	<.01
FFQ Year 2[4]	5929	26.3	7.6	8669	36.3	7.0	9.9	0.1	<.01
FFQ Year 3[5]	3241	27.7	7.9	4889	37.3	7.1	9.6	0.2	<.01
FFQ Year 4[6]	5055	28.6	8.1	7880	37.6	7.1	9.0	0.1	<.01
FFQ Year 5[7]	5811	29.1	8.2	8997	37.8	7.3	8.7	0.1	<.01
FFQ Year 6[8]	6562	29.7	8.3	10036	37.9	7.2	8.2	0.1	<.01
FFQ Year 7[9]	3752	30.3	8.4	5820	38.1	7.4	7.8	0.2	<.01
FFQ Year 8[10]	1796	30.6	8.5	2945	38.5	7.4	7.9	0.2	<.01
FFQ Year 9[11]	890	31.2	8.3	1344	38.7	7.6	7.4	0.3	<.01
4DFR Baseline	892	32.8	6.4	1351	33.0	6.8	0.2	0.3	0.54
4DFR Year 1	805	21.7	7.3	1171	32.9	6.8	11.3	0.3	<.01
24 Hr Recall, Post-baseline	226	23.0	9.2	262	32.1	7.6	9.2	0.8	<.01
24 Hr Recall, Year 1	221	22.4	7.8	268	32.6	7.7	10.2	0.7	<.01
24 Hr Recall, Year 2	214	23.8	9.7	244	32.5	8.0	8.7	0.8	<.01
24 Hr Recall, Year 3	209	25.1	9.2	249	33.3	8.6	8.2	0.8	<.01
24 Hr Recall, Year 3 Cohort	787	24.8	8.5	1183	33.0	7.6	8.3	0.4	<.01
24 Hr Recall, Year 4	222	25.8	9.2	251	33.4	8.5	7.6	0.8	<.01
24 Hr Recall, Year 5	184	26.3	9.4	236	33.9	8.5	7.6	0.9	<.01
24 Hr Recall, Year 6	134	26.6	9.3	174	34.8	8.4	8.3	1.0	<.01
24 Hr Recall, Year 6 Cohort	656	26.6	9.0	986	33.8	7.9	7.2	0.4	<.01
24 Hr Recall, Year 7	81	28.1	9.5	90	35.0	8.5	6.9	1.4	<.01
Total Energy (kcal)									
FFQ Baseline	19541	1789.1	713.3	29294	1789.4	706.6	0.3	6.6	0.93
FFQ Year 1	18099	1473.9	534.5	26776	1584.3	641.6	110.4	5.8	<.01
FFQ Year 2	5929	1479.4	534.7	8669	1575.8	625.5	96.3	9.9	<.01
FFQ Year 3	3241	1476.1	538.0	4889	1571.6	644.3	95.4	13.7	<.01
FFQ Year 4	5055	1443.2	536.4	7880	1561.9	635.0	118.7	10.8	<.01
FFQ Year 5	5811	1450.9	539.8	8997	1552.5	638.6	101.5	10.1	<.01
FFQ Year 6	6562	1414.4	537.6	10036	1535.9	635.3	121.5	9.5	<.01
FFQ Year 7	3752	1404.8	537.0	5820	1533.8	634.0	129.0	12.5	<.01
FFQ Year 8	1796	1408.8	546.1	2945	1536.2	630.0	127.5	18.0	<.01
FFQ Year 9	890	1394.3	571.9	1344	1503.1	591.1	108.8	25.2	<.01
4DFR Baseline	892	1707.2	454.3	1351	1712.9	459.4	5.7	19.7	0.79
4DFR Year 1	805	1422.8	355.7	1171	1627.0	446.9	204.2	18.9	<.01
24 Hr Recall, Post-baseline	226	1519.8	418.2	262	1652.8	516.5	133.0	43.0	<.01
24 Hr Recall, Year 1	221	1482.1	417.8	268	1635.8	477.0	153.6	41.0	<.01
24 Hr Recall, Year 2	214	1436.4	430.0	244	1603.8	523.4	167.4	45.1	<.01
24 Hr Recall, Year 3	209	1443.3	427.8	249	1589.2	504.2	145.9	44.2	<.01
24 Hr Recall, Year 3 Cohort	787	1431.8	391.6	1183	1589.9	489.3	158.1	20.8	<.01
24 Hr Recall, Year 4	222	1431.8	395.7	251	1537.2	461.8	105.4	39.8	0.02
24 Hr Recall, Year 5	184	1377.1	448.8	236	1569.7	512.0	192.6	47.7	<.01
24 Hr Recall, Year 6	134	1410.9	485.4	174	1648.6	537.0	237.7	59.2	<.01
24 Hr Recall, Year 6 Cohort	656	1396.1	393.1	986	1548.7	481.8	152.6	22.6	<.01
24 Hr Recall, Year 7	81	1358.5	393.5	90	1546.7	479.2	188.2	67.5	0.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 4954 (27%) Intervention women had <=20% energy from fat at year 1.
[4] 1270 (21%) Intervention women had <=20% energy from fat at year 2.
[5] 566 (17%) Intervention women had <=20% energy from fat at year 3.
[6] 769 (15%) Intervention women had <=20% energy from fat at year 4.
[7] 785 (14%) Intervention women had <=20% energy from fat at year 5.
[8] 719 (11%) Intervention women had <=20% energy from fat at year 6.
[9] 390 (10%) Intervention women had <=20% energy from fat at year 7.
[10] 189 (11%) Intervention women had <=20% energy from fat at year 8.
[11] 64 (7%) Intervention women had <=20% energy from fat at year 9

Table 3.2 (continued)
Nutrient Intake Monitoring

Data as of: February 29, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Total Fat (g)									
FFQ Baseline	19541	77.9	35.3	29294	77.8	34.7	0.0	0.3	0.87
FFQ Year 1	18099	41.5	21.8	26776	64.5	31.7	23.0	0.3	<.01
FFQ Year 2	5929	43.4	22.3	8669	64.5	31.3	21.0	0.5	<.01
FFQ Year 3	3241	45.8	23.7	4889	66.0	32.5	20.2	0.7	<.01
FFQ Year 4	5055	46.2	23.9	7880	66.2	32.2	20.0	0.5	<.01
FFQ Year 5	5811	47.4	24.5	8997	66.2	32.8	18.9	0.5	<.01
FFQ Year 6	6562	46.9	23.9	10036	65.6	32.5	18.7	0.5	<.01
FFQ Year 7	3752	47.7	25.2	5820	66.0	32.8	18.3	0.6	<.01
FFQ Year 8	1796	48.3	25.2	2945	66.6	32.4	18.2	0.9	<.01
FFQ Year 9	890	48.9	27.2	1344	65.3	30.7	16.4	1.3	<.01
4DFR Baseline	892	63.0	23.6	1351	63.8	24.6	0.8	1.0	0.71
4DFR Year 1	805	34.1	14.5	1171	60.4	23.5	26.3	0.9	<.01
24 Hr Recall, Post-baseline	226	39.6	21.9	262	60.5	26.9	20.9	2.2	<.01
24 Hr Recall, Year 1	221	36.9	17.1	268	60.6	25.1	23.7	2.0	<.01
24 Hr Recall, Year 2	214	38.8	22.6	244	59.3	27.2	20.5	2.4	<.01
24 Hr Recall, Year 3	209	40.9	21.2	249	60.3	27.9	19.4	2.4	<.01
24 Hr Recall, Year 3 Cohort	787	39.8	18.7	1183	59.9	25.6	20.0	1.1	<.01
24 Hr Recall, Year 4	222	41.4	20.1	251	58.7	25.8	17.2	2.1	<.01
24 Hr Recall, Year 5	184	40.8	21.2	236	60.6	27.7	19.8	2.5	<.01
24 Hr Recall, Year 6	134	42.4	23.7	174	65.4	30.0	23.0	3.2	<.01
24 Hr Recall, Year 6 Cohort	656	41.7	20.0	986	59.8	26.5	18.1	1.2	<.01
24 Hr Recall. Year 7	81	43.5	22.3	90	60.6	24.6	17.1	3.6	<.01
Saturated Fat (g)									
FFQ Baseline	19541	27.4	13.4	29294	27.3	13.2	0.1	0.1	0.85
FFQ Year 1	18099	14.2	8.1	26776	22.5	11.9	8.4	0.1	<.01
FFQ Year 2	5929	14.8	8.2	8669	22.5	11.7	7.7	0.2	<.01
FFQ Year 3	3241	15.5	8.9	4889	22.9	12.2	7.4	0.2	<.01
FFQ Year 4	5055	15.7	8.9	7880	23.1	12.2	7.4	0.2	<.01
FFQ Year 5	5811	16.2	9.1	8997	23.2	12.4	7.0	0.2	<.01
FFQ Year 6	6562	15.9	8.8	10036	22.9	12.3	7.0	0.2	<.01
FFQ Year 7	3752	16.4	9.5	5820	23.1	12.6	6.7	0.2	<.01
FFQ Year 8	1796	16.5	9.3	2945	23.4	12.6	6.9	0.3	<.01
FFQ Year 9	890	16.7	9.9	1344	22.9	11.4	6.2	0.5	<.01
4DFR Baseline	892	20.6	8.9	1351	20.9	9.3	0.3	0.4	0.72
4DFR Year 1	805	10.6	5.2	1171	19.5	8.3	9.0	0.3	<.01
24 Hr Recall, Post-baseline	226	12.9	7.9	262	20.1	9.6	7.2	0.8	<.01
24 Hr Recall, Year 1	221	11.7	6.2	268	20.1	10.1	8.4	0.8	<.01
24 Hr Recall, Year 2	214	12.3	8.2	244	19.5	9.9	7.2	0.9	<.01
24 Hr Recall, Year 3	209	13.4	7.7	249	20.3	10.8	6.9	0.9	<.01
24 Hr Recall, Year 3 Cohort	787	12.4	6.8	1183	19.7	9.3	7.3	0.4	<.01
24 Hr Recall, Year 4	222	13.4	7.6	251	19.7	10.2	6.3	0.8	<.01
24 Hr Recall, Year 5	184	13.0	7.0	236	20.4	10.3	7.4	0.9	<.01
24 Hr Recall, Year 6	134	13.3	8.2	174	21.4	11.4	8.1	1.2	<.01
24 Hr Recall, Year 6 Cohort	656	13.1	7.1	986	19.5	9.7	6.4	0.4	<.01
24 Hr Recall, Year 7	81	13.5	7.9	90	19.7	9.0	6.2	1.3	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.2 (continued)
Nutrient Intake Monitoring

Data as of: February 29, 2004

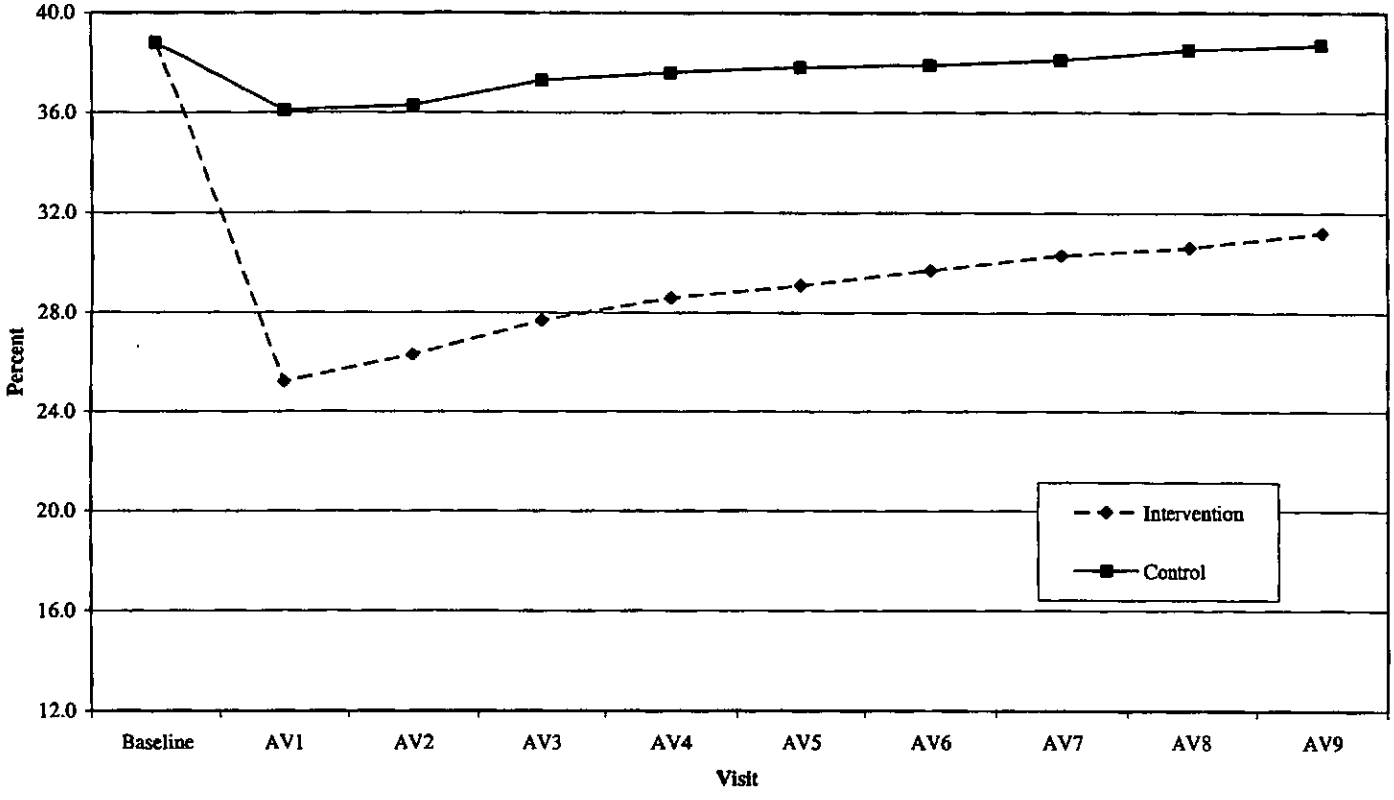
	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Polyunsaturated Fat (g)									
FFQ Baseline	19541	15.3	7.6	29294	15.3	7.6	0.0	0.1	0.79
FFQ Year 1	18099	7.9	4.4	26776	12.5	6.7	4.6	0.1	<.01
FFQ Year 2	5929	8.3	4.5	8669	12.4	6.5	4.1	0.1	<.01
FFQ Year 3	3241	8.8	4.7	4889	12.8	6.8	4.0	0.1	<.01
FFQ Year 4	5055	9.0	4.9	7880	12.8	6.7	3.8	0.1	<.01
FFQ Year 5	5811	9.2	5.0	8997	12.8	6.9	3.7	0.1	<.01
FFQ Year 6	6562	9.2	5.0	10036	12.7	6.7	3.5	0.1	<.01
FFQ Year 7	3752	9.2	5.1	5820	12.8	6.7	3.6	0.1	<.01
FFQ Year 8	1796	9.3	5.1	2945	12.7	6.5	3.4	0.2	<.01
FFQ Year 9	890	9.5	5.6	1344	12.6	6.5	3.2	0.3	<.01
4DFR Baseline	892	13.1	5.8	1351	13.5	6.1	0.3	0.3	0.40
4DFR Year 1	805	7.4	3.4	1171	12.7	6.2	5.3	0.2	<.01
24 Hr Recall, Post-baseline	226	8.3	5.0	262	12.6	7.3	4.3	0.6	<.01
24 Hr Recall, Year 1	221	7.8	4.4	268	12.4	6.3	4.6	0.5	<.01
24 Hr Recall, Year 2	214	8.3	5.7	244	12.5	7.6	4.2	0.6	<.01
24 Hr Recall, Year 3	209	8.5	5.5	249	12.2	6.6	3.8	0.6	<.01
24 Hr Recall, Year 3 Cohort	787	8.7	4.6	1183	12.2	6.9	3.6	0.3	<.01
24 Hr Recall, Year 4	222	8.7	4.9	251	11.9	6.9	3.1	0.6	<.01
24 Hr Recall, Year 5	184	8.7	6.0	236	12.1	7.6	3.4	0.7	<.01
24 Hr Recall, Year 6	134	9.3	6.4	174	13.8	7.4	4.6	0.8	<.01
24 Hr Recall, Year 6 Cohort	656	8.8	4.7	986	12.3	6.3	3.5	0.3	<.01
24 Hr Recall, Year 7	81	9.4	5.8	90	12.9	6.3	3.5	0.9	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	19470	3.6	1.8	29216	3.6	1.8	0.0	0.0	0.69
FFQ Year 1	18018	5.0	2.3	26694	3.8	2.0	1.2	0.0	<.01
FFQ Year 2	5905	5.1	2.4	8637	3.9	2.0	1.2	0.0	<.01
FFQ Year 3	3235	5.2	2.5	4875	3.9	2.0	1.3	0.1	<.01
FFQ Year 4	5045	5.1	2.4	7866	3.8	2.0	1.3	0.0	<.01
FFQ Year 5	5788	5.1	2.5	8971	3.8	2.1	1.2	0.0	<.01
FFQ Year 6	6538	5.0	2.4	10011	3.8	2.0	1.2	0.0	<.01
FFQ Year 7	3732	4.8	2.4	5806	3.8	2.0	1.0	0.0	<.01
FFQ Year 8	1784	4.9	2.4	2934	3.8	2.0	1.1	0.1	<.01
FFQ Year 9	881	4.7	2.4	1337	3.7	2.0	1.0	0.1	<.01
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	19468	4.7	2.5	29214	4.8	2.5	0.0	0.0	0.42
FFQ Year 1	18014	5.1	2.7	26684	4.2	2.3	0.8	0.0	<.01
FFQ Year 2	5904	4.9	2.5	8631	4.1	2.2	0.7	0.0	<.01
FFQ Year 3	3234	4.6	2.5	4870	4.0	2.2	0.7	0.1	<.01
FFQ Year 4	5041	4.4	2.4	7854	3.9	2.2	0.5	0.0	<.01
FFQ Year 5	5784	4.3	2.3	8959	3.8	2.1	0.5	0.0	<.01
FFQ Year 6	6535	4.1	2.3	9995	3.7	2.1	0.4	0.0	<.01
FFQ Year 7	3730	3.9	2.2	5798	3.6	2.1	0.3	0.0	<.01
FFQ Year 8	1784	3.9	2.2	2928	3.6	2.1	0.3	0.1	<.01
FFQ Year 9	879	3.8	2.2	1333	3.5	1.9	0.3	0.1	<.01

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

Figure 3.1
Nutrient Intake

Data as of: February 29, 2004

% Energy from Fat[1]



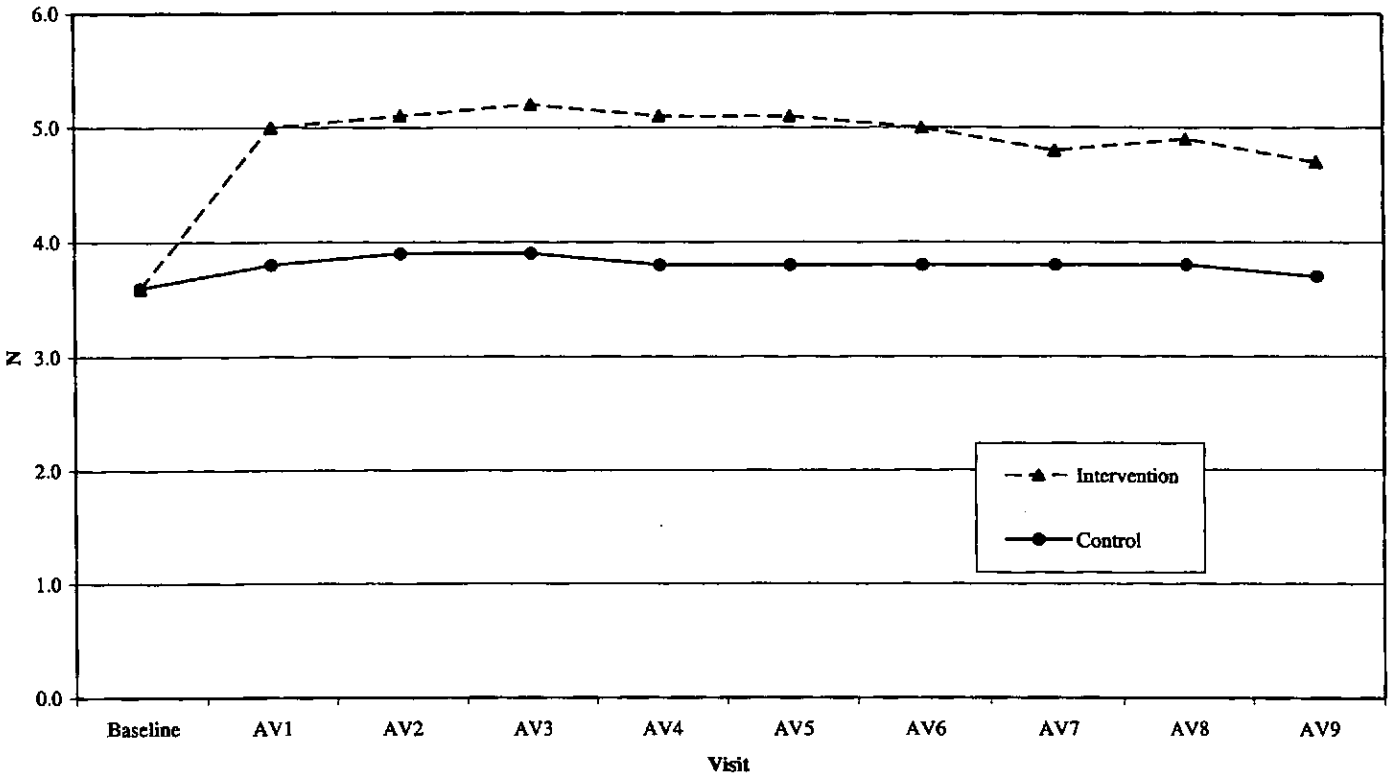
(continues)

[1] Baseline % energy from fat values are about 3% higher in both groups due to the use of FFQ % energy from fat as an exclusionary criterion during screening.

Figure 3.1 (continued)
Nutrient Intake

Data as of: February 29, 2004

Fruit & Vegetable Servings per Day



Grain Servings per Day

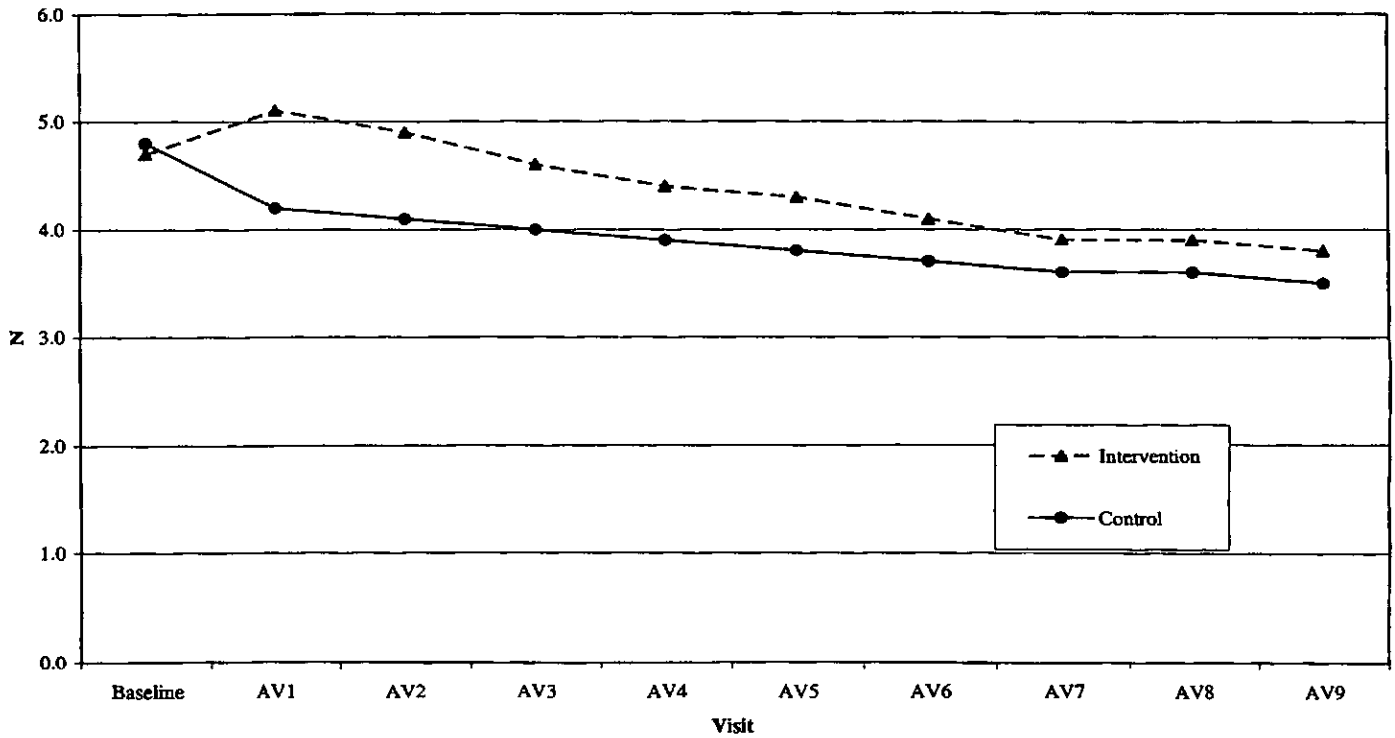


Table 3.3
Nutrient Intake Monitoring in American Indian/Alaskan Native Women

Data as of: February 29, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	88	39.5	5.7	114	40.0	5.2	0.5	0.8	0.49
FFQ Year 1[3]	73	27.5	8.9	96	38.0	8.0	10.5	1.3	<.01
FFQ Year 2[4]	28	26.9	8.8	32	38.2	6.8	11.3	2.0	<.01
FFQ Year 3[5]	18	31.3	8.9	41	38.0	7.0	6.7	2.1	<.01
FFQ Year 4[6]	23	30.3	9.3	28	39.9	7.6	9.6	2.4	<.01
FFQ Year 5[7]	19	27.6	7.6	16	39.9	7.8	12.3	2.6	<.01
FFQ Year 6[8]	35	31.2	7.5	45	41.7	7.2	10.5	1.7	<.01
FFQ Year 7[9]	20	28.2	8.6	17	40.1	8.2	11.8	2.8	<.01
FFQ Year 8[10]	6	36.6	8.4	17	39.6	7.1	3.0	3.5	0.46
FFQ Year 9[11]	3	28.7	6.3	2	39.8	2.1	11.2	4.8	0.08
4DFR Baseline	24	34.0	6.7	44	33.4	7.8	0.6	1.9	0.73
4DFR Year 1	18	20.5	6.2	32	34.6	7.4	14.2	2.1	<.01
Total Energy (kcal)									
FFQ Baseline	88	1717.5	795.9	114	1771.7	718.2	54.3	106.8	0.42
FFQ Year 1	73	1631.3	689.6	96	1545.5	753.4	85.8	112.8	0.52
FFQ Year 2	28	1508.4	565.8	32	1554.0	706.9	45.6	166.9	0.95
FFQ Year 3	18	1520.0	614.4	41	1589.0	704.1	69.0	191.9	0.83
FFQ Year 4	23	1441.3	478.9	28	1821.1	932.9	379.7	214.8	0.09
FFQ Year 5	19	1673.2	661.5	16	1366.0	724.8	307.2	234.5	0.10
FFQ Year 6	35	1129.1	513.2	45	1579.3	774.8	450.2	151.8	<.01
FFQ Year 7	20	1460.6	456.5	17	1784.2	943.4	323.6	237.9	0.24
FFQ Year 8	6	1415.7	324.4	17	1613.6	705.6	197.9	302.0	0.66
FFQ Year 9	3	1594.3	755.7	2	1705.6	323.0	111.3	588.5	0.70
4DFR Baseline	24	1524.3	426.0	44	1672.0	606.8	147.7	139.7	0.47
4DFR Year 1	18	1283.9	418.7	32	1631.9	613.0	348.1	162.7	0.04
Total Fat (g)									
FFQ Baseline	88	76.5	40.3	114	79.3	35.6	2.8	5.4	0.34
FFQ Year 1	73	50.3	29.6	96	67.1	43.6	16.8	5.9	<.01
FFQ Year 2	28	45.8	29.0	32	68.5	40.0	22.7	9.1	<.01
FFQ Year 3	18	56.6	35.4	41	68.6	35.7	11.9	10.1	0.22
FFQ Year 4	23	48.9	21.7	28	81.3	44.5	32.4	10.2	<.01
FFQ Year 5	19	52.1	26.7	16	63.6	43.0	11.5	11.9	0.46
FFQ Year 6	35	38.9	21.0	45	73.5	41.4	34.6	7.7	<.01
FFQ Year 7	20	45.2	19.9	17	78.2	37.7	33.0	9.7	<.01
FFQ Year 8	6	56.5	12.6	17	72.8	36.9	16.3	15.6	0.37
FFQ Year 9	3	50.7	29.4	2	75.8	18.3	25.1	24.0	0.27
4DFR Baseline	24	57.4	17.5	44	63.8	30.8	6.4	6.8	0.83
4DFR Year 1	18	29.4	12.9	32	64.9	33.0	35.5	8.1	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 14 (19%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 1.
[4] 6 (21%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 2.
[5] 1 (6%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 3.
[6] 5 (22%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 4.
[7] 3 (16%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 5.
[8] 3 (9%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 6.
[9] 4 (20%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 7.
[10] 0 (0%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 8.
[11] 0 (0%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 9.

Table 3.3 (continued)
Nutrient Intake Monitoring in American Indian/Alaskan Native Women

Data as of: February 29, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	88	26.9	14.2	114	27.9	14.1	1.0	2.0	0.42
FFQ Year 1	73	17.4	11.0	96	23.7	18.0	6.2	2.4	<.01
FFQ Year 2	28	15.5	9.9	32	23.3	14.9	7.8	3.3	<.01
FFQ Year 3	18	19.8	13.9	41	22.9	11.9	3.0	3.5	0.27
FFQ Year 4	23	17.2	8.4	28	28.3	16.6	11.2	3.8	<.01
FFQ Year 5	19	18.3	11.6	16	22.0	17.0	3.7	4.8	0.50
FFQ Year 6	35	12.7	7.3	45	24.8	13.8	12.1	2.6	<.01
FFQ Year 7	20	15.6	7.4	17	27.3	15.4	11.7	3.9	<.01
FFQ Year 8	6	18.4	6.9	17	24.4	13.4	5.9	5.8	0.39
FFQ Year 9	3	18.9	13.0	2	25.3	6.4	6.5	10.3	0.39
4DFR Baseline	24	19.1	6.9	44	21.4	12.3	2.4	2.7	0.87
4DFR Year 1	18	9.0	4.2	32	21.0	10.9	12.0	2.7	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	88	15.2	9.5	114	15.3	7.6	0.1	1.2	0.48
FFQ Year 1	73	9.4	6.3	96	12.7	8.5	3.3	1.2	<.01
FFQ Year 2	28	8.9	6.6	32	14.0	8.8	5.1	2.0	<.01
FFQ Year 3	18	10.2	5.8	41	14.0	7.9	3.8	2.1	0.10
FFQ Year 4	23	9.3	4.7	28	15.6	8.9	6.3	2.1	<.01
FFQ Year 5	19	9.7	3.9	16	11.8	8.2	2.0	2.1	0.64
FFQ Year 6	35	7.9	4.8	45	14.7	10.0	6.8	1.8	<.01
FFQ Year 7	20	8.3	4.0	17	14.7	7.5	6.3	1.9	<.01
FFQ Year 9	6	12.2	2.4	17	15.4	8.2	3.2	3.4	0.46
FFQ Year 9	3	7.5	4.1	2	14.1	3.8	6.6	3.6	0.14
4DFR Baseline	24	11.5	4.6	44	12.2	6.2	0.7	1.5	0.92
4DFR Year 1	18	6.9	3.8	32	13.6	9.6	6.7	2.4	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	88	3.5	1.9	114	3.0	1.6	0.4	0.2	0.23
FFQ Year 1	73	5.1	2.9	96	3.5	2.1	1.6	0.4	<.01
FFQ Year 2	28	5.2	3.3	32	3.3	1.6	1.9	0.7	0.05
FFQ Year 3	18	4.9	2.0	41	3.8	2.3	1.0	0.6	0.03
FFQ Year 4	23	5.1	3.1	28	4.0	2.1	1.1	0.7	0.25
FFQ Year 5	19	5.6	2.4	16	2.7	1.4	2.8	0.7	<.01
FFQ Year 6	35	4.4	2.7	45	3.1	1.9	1.3	0.5	0.03
FFQ Year 7	20	5.7	3.2	17	4.1	2.4	1.7	0.9	0.10
FFQ Year 8	6	4.4	2.4	17	3.4	2.2	1.0	1.1	0.30
FFQ Year 9	3	4.5	1.4	2	3.3	2.2	1.1	1.6	0.59
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	88	4.5	2.5	114	4.7	2.7	0.2	0.4	0.49
FFQ Year 1	73	5.5	3.4	96	4.2	2.3	1.3	0.4	0.02
FFQ Year 2	28	5.5	3.0	32	4.2	2.9	1.3	0.8	0.15
FFQ Year 3	18	4.2	2.6	41	4.2	2.5	0.0	0.7	0.76
FFQ Year 4	23	4.2	2.2	28	4.5	2.8	0.3	0.7	0.72
FFQ Year 5	19	4.6	2.4	16	3.8	2.2	0.8	0.8	0.26
FFQ Year 6	35	3.2	2.4	45	3.9	2.7	0.7	0.6	0.24
FFQ Year 7	20	4.4	2.6	17	4.1	1.8	0.2	0.7	1.00
FFQ Year 8	6	3.2	1.6	17	3.3	1.9	0.1	0.9	0.96
FFQ Year 9	3	5.0	2.4	2	5.8	3.4	0.8	2.5	0.79

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.3 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women

Data as of: February 29, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	431	37.7	4.4	674	38.4	4.7	0.7	0.3	0.02
FFQ Year 1[3]	409	25.8	7.3	629	36.1	6.6	10.3	0.4	<.01
FFQ Year 2[4]	147	27.2	7.4	213	36.1	6.9	8.9	0.8	<.01
FFQ Year 3[5]	107	28.1	7.5	152	36.3	6.4	8.2	0.9	<.01
FFQ Year 4[6]	106	29.6	8.3	189	37.4	6.6	7.8	0.9	<.01
FFQ Year 5[7]	136	29.0	8.2	221	36.9	7.1	7.9	0.8	<.01
FFQ Year 6[8]	155	29.3	7.8	264	38.0	6.5	8.6	0.7	<.01
FFQ Year 7[9]	62	29.1	8.2	110	37.0	7.4	7.8	1.2	<.01
FFQ Year 8[10]	17	30.2	7.8	35	37.4	6.2	7.2	2.0	<.01
FFQ Year 9[11]	5	27.0	6.7	7	34.7	7.3	7.7	4.1	0.09
4DFR Baseline	70	30.2	5.4	104	31.4	6.8	1.2	1.0	0.18
4DFR Year 1	68	21.5	7.6	88	31.6	5.8	10.1	1.1	<.01
Total Energy (kcal)									
FFQ Baseline	431	1699.9	722.7	674	1674.9	711.3	25.0	44.1	0.50
FFQ Year 1	409	1501.7	587.0	629	1523.7	635.3	22.0	39.2	0.94
FFQ Year 2	147	1512.0	636.7	213	1500.3	777.2	11.7	77.6	0.24
FFQ Year 3	107	1496.2	630.5	152	1414.8	582.8	81.5	76.1	0.28
FFQ Year 4	106	1475.7	616.6	189	1507.8	612.0	32.1	74.5	0.97
FFQ Year 5	136	1513.9	636.6	221	1499.4	809.9	14.6	81.6	0.24
FFQ Year 6	155	1392.9	539.5	264	1530.1	766.3	137.2	70.0	0.12
FFQ Year 7	62	1348.4	600.6	110	1405.4	562.0	57.0	91.5	0.46
FFQ Year 8	17	1361.0	624.3	35	1333.8	448.8	27.2	151.2	0.97
FFQ Year 9	5	1592.2	200.2	7	920.7	302.7	671.5	156.0	<.01
4DFR Baseline	70	1683.3	400.1	104	1732.3	387.9	48.9	60.7	0.38
4DFR Year 1	68	1524.9	374.1	88	1619.6	397.2	94.7	62.5	0.12
Total Fat (g)									
FFQ Baseline	431	71.9	34.1	674	72.2	34.8	0.4	2.1	0.99
FFQ Year 1	409	43.5	23.5	629	62.3	31.4	18.9	1.8	<.01
FFQ Year 2	147	46.1	24.6	213	61.1	35.6	15.0	3.4	<.01
FFQ Year 3	107	47.3	28.0	152	57.7	28.0	10.3	3.5	<.01
FFQ Year 4	106	49.5	28.8	189	63.3	29.6	13.8	3.6	<.01
FFQ Year 5	136	50.4	30.3	221	62.7	39.0	12.2	3.9	<.01
FFQ Year 6	155	45.4	22.7	264	65.1	36.3	19.8	3.2	<.01
FFQ Year 7	62	44.1	26.1	110	58.8	28.9	14.7	4.4	<.01
FFQ Year 8	17	46.1	27.7	35	56.5	24.3	10.4	7.5	0.10
FFQ Year 9	5	48.9	16.3	7	35.9	15.6	12.9	9.3	0.22
4DFR Baseline	70	57.1	19.1	104	61.8	23.4	4.7	3.4	0.24
4DFR Year 1	68	36.6	17.4	88	57.6	19.9	21.0	3.0	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 99 (24%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 1.
[4] 24 (16%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 2.
[5] 18 (17%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 3.
[6] 12 (11%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 4.
[7] 18 (13%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 5.
[8] 15 (10%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 6.
[9] 8 (13%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 7.
[10] 3 (18%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 8.
[11] 1 (20%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 9.

Table 3.3 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women

Data as of: February 29, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	431	22.8	12.0	674	22.9	12.0	0.1	0.7	0.94
FFQ Year 1	409	13.5	8.0	629	19.5	10.8	6.0	0.6	<.01
FFQ Year 2	147	14.3	8.5	213	19.2	11.9	5.0	1.1	<.01
FFQ Year 3	107	14.8	10.1	152	18.1	9.8	3.3	1.3	<.01
FFQ Year 4	106	15.4	10.1	189	19.9	9.6	4.5	1.2	<.01
FFQ Year 5	136	16.0	10.2	221	19.7	13.4	3.7	1.3	<.01
FFQ Year 6	155	14.1	7.9	264	20.7	12.8	6.6	1.1	<.01
FFQ Year 7	62	14.4	10.1	110	18.8	10.5	4.4	1.6	<.01
FFQ Year 8	17	14.4	8.4	35	18.0	8.5	3.7	2.5	0.09
FFQ Year 9	5	15.9	5.7	7	11.0	4.4	4.9	2.9	0.18
4DFR Baseline	70	17.2	7.1	104	18.8	8.4	1.7	1.2	0.26
4DFR Year 1	68	10.5	5.5	88	17.7	7.2	7.2	1.0	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	431	15.6	7.4	674	15.7	7.8	0.0	0.5	0.54
FFQ Year 1	409	9.1	5.0	629	13.6	7.2	4.5	0.4	<.01
FFQ Year 2	147	9.8	5.5	213	13.0	8.0	3.2	0.8	<.01
FFQ Year 3	107	10.1	5.7	152	12.1	6.1	2.0	0.7	<.01
FFQ Year 4	106	10.8	6.2	189	13.4	6.5	2.6	0.8	<.01
FFQ Year 5	136	10.6	7.4	221	13.5	8.1	2.8	0.9	<.01
FFQ Year 6	155	9.7	5.0	264	13.7	7.3	4.0	0.7	<.01
FFQ Year 7	62	9.0	5.2	110	12.2	6.3	3.2	0.9	<.01
FFQ Year 8	17	9.3	6.2	35	12.0	5.9	2.8	1.8	0.06
FFQ Year 9	5	10.6	3.9	7	7.9	3.9	2.7	2.3	0.26
4DFR Baseline	70	13.1	5.3	104	14.6	6.5	1.5	0.9	0.12
4DFR Year 1	68	8.8	4.4	88	12.9	5.9	4.1	0.9	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	429	3.4	1.7	674	3.3	1.9	0.1	0.1	0.26
FFQ Year 1	407	4.7	2.4	629	3.5	1.9	1.2	0.1	<.01
FFQ Year 2	146	4.8	2.7	213	3.4	1.9	1.4	0.2	<.01
FFQ Year 3	107	5.0	2.5	152	3.4	2.1	1.5	0.3	<.01
FFQ Year 4	105	4.7	2.4	189	3.2	1.9	1.5	0.3	<.01
FFQ Year 5	136	4.8	2.3	221	3.6	2.0	1.3	0.2	<.01
FFQ Year 6	154	4.8	2.5	264	3.4	2.0	1.3	0.2	<.01
FFQ Year 7	62	4.8	2.3	110	3.5	1.9	1.3	0.3	<.01
FFQ Year 8	17	4.8	2.6	35	3.1	1.2	1.7	0.5	0.06
FFQ Year 9	5	4.7	1.1	7	2.5	1.4	2.2	0.7	<.01
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	429	4.8	2.5	674	4.6	2.2	0.2	0.1	0.47
FFQ Year 1	407	5.6	2.6	629	4.4	2.1	1.3	0.1	<.01
FFQ Year 2	146	5.2	2.5	213	4.1	2.3	1.1	0.3	<.01
FFQ Year 3	107	5.0	2.4	152	4.1	2.1	0.9	0.3	<.01
FFQ Year 4	105	4.9	2.3	189	4.3	2.1	0.7	0.3	<.01
FFQ Year 5	136	4.9	2.2	221	4.2	2.8	0.7	0.3	<.01
FFQ Year 6	153	4.5	2.2	264	4.2	2.5	0.3	0.2	0.08
FFQ Year 7	62	4.1	2.1	110	3.8	1.7	0.3	0.3	0.54
FFQ Year 8	17	4.2	2.1	35	3.8	1.7	0.4	0.5	0.72
FFQ Year 9	5	5.7	1.6	7	2.9	1.4	2.8	0.9	0.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.3 (continued)
Nutrient Intake Monitoring in Black/African American Women

Data as of: February 29, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	2135	39.7	5.3	3127	39.9	5.2	0.1	0.1	0.41
FFQ Year 1[3]	1860	28.0	8.4	2629	36.9	7.4	8.8	0.2	<.01
FFQ Year 2[4]	613	29.4	8.0	829	36.4	7.3	7.0	0.4	<.01
FFQ Year 3[5]	350	29.4	7.9	514	38.2	7.2	8.8	0.5	<.01
FFQ Year 4[6]	485	30.7	8.3	775	37.5	7.4	6.8	0.4	<.01
FFQ Year 5[7]	582	31.3	8.6	861	37.4	7.4	6.1	0.4	<.01
FFQ Year 6[8]	770	31.2	8.0	1129	37.8	7.6	6.7	0.4	<.01
FFQ Year 7[9]	314	31.8	8.0	481	37.6	7.0	5.8	0.5	<.01
FFQ Year 8[10]	184	32.5	8.1	245	37.6	7.3	5.2	0.7	<.01
FFQ Year 9[11]	66	33.1	7.9	109	37.7	8.1	4.6	1.3	<.01
4DFR Baseline	243	34.0	6.7	371	34.2	6.9	0.2	0.6	0.76
4DFR Year 1	219	23.5	7.9	307	34.2	7.0	10.8	0.7	<.01
Total Energy (kcal)									
FFQ Baseline	2135	1744.4	826.9	3127	1739.4	834.9	5.0	23.3	0.72
FFQ Year 1	1860	1382.7	633.4	2629	1492.4	774.6	109.7	21.8	<.01
FFQ Year 2	613	1393.4	717.5	829	1449.0	724.7	55.6	38.4	0.36
FFQ Year 3	350	1386.7	631.4	514	1537.1	791.3	150.3	50.6	0.01
FFQ Year 4	485	1342.7	622.4	775	1436.1	743.8	93.4	40.5	0.09
FFQ Year 5	582	1353.6	641.5	861	1381.7	697.5	28.0	36.2	0.51
FFQ Year 6	770	1305.8	574.0	1129	1393.5	751.0	87.7	32.0	0.13
FFQ Year 7	314	1285.6	585.7	481	1362.5	700.2	76.9	47.7	0.28
FFQ Year 8	184	1243.4	609.6	245	1371.6	745.1	128.2	67.3	0.11
FFQ Year 9	66	1270.3	688.2	109	1265.0	567.8	5.3	96.0	0.67
4DFR Baseline	243	1704.3	526.0	371	1651.0	478.3	53.4	41.1	0.32
4DFR Year 1	219	1345.6	341.6	307	1584.5	481.8	239.0	38.0	<.01
Total Fat (g)									
FFQ Baseline	2135	77.7	40.7	3127	77.8	41.3	0.1	1.2	0.92
FFQ Year 1	1860	43.6	26.8	2629	62.3	37.2	18.7	1.0	<.01
FFQ Year 2	613	46.4	32.5	829	60.1	36.0	13.6	1.8	<.01
FFQ Year 3	350	46.1	27.0	514	66.3	38.6	20.2	2.4	<.01
FFQ Year 4	485	46.2	26.7	775	60.9	35.7	14.7	1.9	<.01
FFQ Year 5	582	47.5	27.7	861	58.7	35.2	11.2	1.7	<.01
FFQ Year 6	770	45.8	25.7	1129	59.7	38.2	13.9	1.6	<.01
FFQ Year 7	314	45.4	25.0	481	58.2	34.7	12.9	2.3	<.01
FFQ Year 8	184	45.4	28.3	245	58.0	35.9	12.6	3.2	<.01
FFQ Year 9	66	47.5	30.4	109	53.6	28.1	6.0	4.5	0.06
4DFR Baseline	243	65.1	25.7	371	63.9	26.3	1.2	2.2	0.54
4DFR Year 1	219	34.9	14.7	307	61.5	25.7	26.6	1.9	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 323 (17%) Black/African American Intervention women had <=20% energy from fat at year 1.
[4] 80 (13%) Black/African American Intervention women had <=20% energy from fat at year 2.
[5] 46 (13%) Black/African American Intervention women had <=20% energy from fat at year 3.
[6] 54 (11%) Black/African American Intervention women had <=20% energy from fat at year 4.
[7] 46 (8%) Black/African American Intervention women had <=20% energy from fat at year 5.
[8] 65 (8%) Black/African American Intervention women had <=20% energy from fat at year 6.
[9] 25 (8%) Black/African American Intervention women had <=20% energy from fat at year 7.
[10] 11 (6%) Black/African American Intervention women had <=20% energy from fat at year 8.
[11] 6 (9%) Black/African American Intervention women had <=20% energy from fat at year 9.

Table 3.3 (continued)
Nutrient Intake Monitoring in Black/African American Women

Data as of: February 29, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	2135	25.8	14.3	3127	25.9	14.7	0.1	0.4	0.91
FFQ Year 1	1860	14.3	9.2	2629	20.5	12.8	6.2	0.3	<.01
FFQ Year 2	613	15.3	11.8	829	19.8	12.3	4.5	0.6	<.01
FFQ Year 3	350	15.0	9.5	514	21.8	13.4	6.8	0.8	<.01
FFQ Year 4	485	14.9	9.3	775	20.0	12.4	5.2	0.7	<.01
FFQ Year 5	582	15.4	9.5	861	19.2	12.4	3.8	0.6	<.01
FFQ Year 6	770	14.7	8.6	1129	19.4	13.1	4.7	0.5	<.01
FFQ Year 7	314	14.7	8.7	481	19.1	12.0	4.4	0.8	<.01
FFQ Year 8	184	14.6	9.6	245	18.9	13.1	4.3	1.1	<.01
FFQ Year 9	66	15.1	10.1	109	17.5	9.7	2.4	1.5	0.04
4DFR Baseline	243	20.3	9.3	371	20.2	9.1	0.1	0.8	0.96
4DFR Year 1	219	10.6	5.2	307	18.7	8.2	8.1	0.6	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	2135	16.0	8.9	3127	16.0	8.9	0.0	0.3	0.98
FFQ Year 1	1860	8.7	5.6	2629	12.7	8.0	4.0	0.2	<.01
FFQ Year 2	613	9.2	6.2	829	12.1	7.5	2.9	0.4	<.01
FFQ Year 3	350	9.3	5.6	514	13.4	8.0	4.1	0.5	<.01
FFQ Year 4	485	9.5	5.7	775	12.4	7.6	2.9	0.4	<.01
FFQ Year 5	582	9.6	5.8	861	12.1	7.8	2.5	0.4	<.01
FFQ Year 6	770	9.4	5.7	1129	12.3	8.1	2.9	0.3	<.01
FFQ Year 7	314	9.3	5.5	481	11.9	7.4	2.6	0.5	<.01
FFQ Year 8	184	9.3	6.0	245	11.9	7.5	2.7	0.7	<.01
FFQ Year 9	66	9.6	6.2	109	10.8	6.0	1.1	0.9	0.08
4DFR Baseline	243	14.5	6.7	371	13.8	6.7	0.7	0.6	0.15
4DFR Year 1	219	7.6	3.2	307	13.7	6.9	6.1	0.5	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	2132	3.3	1.9	3123	3.2	1.9	0.0	0.1	0.73
FFQ Year 1	1854	4.5	2.6	2623	3.4	2.1	1.1	0.1	<.01
FFQ Year 2	612	4.5	2.6	824	3.5	2.2	1.0	0.1	<.01
FFQ Year 3	350	4.7	2.7	514	3.7	2.3	1.0	0.2	<.01
FFQ Year 4	485	4.8	2.7	775	3.4	2.1	1.3	0.1	<.01
FFQ Year 5	579	4.6	2.7	860	3.5	2.1	1.1	0.1	<.01
FFQ Year 6	770	4.6	2.6	1127	3.5	2.1	1.1	0.1	<.01
FFQ Year 7	313	4.4	2.6	480	3.5	2.1	1.0	0.2	<.01
FFQ Year 8	184	4.4	2.6	243	3.3	2.1	1.1	0.2	<.01
FFQ Year 9	66	4.2	2.5	109	3.5	2.0	0.7	0.3	0.24
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	2132	4.5	2.7	3122	4.4	2.8	0.1	0.1	0.32
FFQ Year 1	1853	4.4	2.8	2621	3.8	2.5	0.6	0.1	<.01
FFQ Year 2	612	4.2	2.6	823	3.7	2.4	0.5	0.1	<.01
FFQ Year 3	350	4.2	2.7	514	3.8	2.5	0.4	0.2	0.01
FFQ Year 4	485	4.0	2.5	773	3.6	2.4	0.4	0.1	<.01
FFQ Year 5	578	3.9	2.5	859	3.4	2.2	0.4	0.1	<.01
FFQ Year 6	770	3.6	2.2	1123	3.4	2.2	0.3	0.1	<.01
FFQ Year 7	313	3.5	2.2	480	3.3	2.3	0.2	0.2	0.10
FFQ Year 8	184	3.4	2.3	242	3.4	2.4	0.0	0.2	0.88
FFQ Year 9	66	3.4	2.2	108	2.9	1.5	0.5	0.3	0.42

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.3 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women

Data as of: February 29, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	751	39.3	5.1	1094	39.0	5.1	0.4	0.2	0.13
FFQ Year 1[3]	617	27.9	8.0	914	36.1	7.4	8.2	0.4	<.01
FFQ Year 2[4]	226	27.7	8.3	304	36.9	7.5	9.2	0.7	<.01
FFQ Year 3[5]	131	29.9	8.9	195	37.2	7.3	7.3	0.9	<.01
FFQ Year 4[6]	163	30.9	8.3	296	36.9	7.2	6.0	0.7	<.01
FFQ Year 5[7]	188	29.9	8.5	302	36.3	7.4	6.3	0.7	<.01
FFQ Year 6[8]	224	30.9	8.2	393	37.2	6.9	6.4	0.6	<.01
FFQ Year 7[9]	110	31.9	9.7	157	37.6	7.2	5.7	1.0	<.01
FFQ Year 8[10]	45	31.2	9.3	73	37.0	8.0	5.8	1.6	<.01
FFQ Year 9[11]	22	33.0	9.4	29	36.0	7.1	2.9	2.3	0.23
4DFR Baseline	96	32.4	5.7	134	32.4	6.5	0.1	0.8	0.95
4DFR Year 1	82	23.1	7.4	110	32.0	7.3	8.9	1.1	<.01
Total Energy (kcal)									
FFQ Baseline	751	1846.5	836.1	1094	1859.3	870.7	12.8	40.6	0.86
FFQ Year 1	617	1417.1	666.7	914	1569.9	862.5	152.8	41.1	<.01
FFQ Year 2	226	1411.2	614.8	304	1625.8	772.1	214.6	62.3	<.01
FFQ Year 3	131	1534.3	638.4	195	1576.7	710.7	42.4	77.1	0.80
FFQ Year 4	163	1385.3	651.8	296	1528.0	756.5	142.7	70.3	0.04
FFQ Year 5	188	1377.7	655.7	302	1584.0	917.3	206.4	76.8	0.03
FFQ Year 6	224	1350.2	661.9	393	1530.5	760.8	180.3	60.8	<.01
FFQ Year 7	110	1301.3	566.6	157	1448.2	798.7	146.9	88.6	0.33
FFQ Year 8	45	1335.6	498.6	73	1405.1	600.2	69.5	106.9	0.72
FFQ Year 9	22	1223.1	654.7	29	1397.5	654.6	174.4	185.1	0.20
4DFR Baseline	96	1643.3	446.4	134	1748.5	460.0	105.2	60.8	0.06
4DFR Year 1	82	1399.8	412.1	110	1627.1	448.8	227.3	63.3	<.01
Total Fat (g)									
FFQ Baseline	751	81.6	41.0	1094	80.8	40.5	0.8	1.9	0.56
FFQ Year 1	617	44.5	27.3	914	64.3	41.2	19.8	1.9	<.01
FFQ Year 2	226	43.7	24.3	304	68.3	38.6	24.5	2.9	<.01
FFQ Year 3	131	52.3	31.8	195	66.1	34.8	13.8	3.8	<.01
FFQ Year 4	163	48.1	27.8	296	63.5	35.4	15.5	3.2	<.01
FFQ Year 5	188	46.9	30.0	302	66.1	44.7	19.1	3.7	<.01
FFQ Year 6	224	46.9	26.9	393	64.1	36.1	17.2	2.8	<.01
FFQ Year 7	110	46.9	28.0	157	60.8	37.0	13.9	4.2	<.01
FFQ Year 8	45	45.8	20.1	73	57.8	29.2	12.0	5.0	0.02
FFQ Year 9	22	45.2	30.9	29	56.9	35.1	11.7	9.4	0.09
4DFR Baseline	96	59.6	20.1	134	64.1	25.6	4.5	3.1	0.22
4DFR Year 1	82	36.4	17.7	110	58.9	24.5	22.5	3.2	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 106 (17%) Hispanic/Latino Intervention women had <=20% energy from fat at year 1.
[4] 45 (20%) Hispanic/Latino Intervention women had <=20% energy from fat at year 2.
[5] 14 (11%) Hispanic/Latino Intervention women had <=20% energy from fat at year 3.
[6] 16 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 4.
[7] 24 (13%) Hispanic/Latino Intervention women had <=20% energy from fat at year 5.
[8] 23 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 6.
[9] 12 (11%) Hispanic/Latino Intervention women had <=20% energy from fat at year 7.
[10] 4 (9%) Hispanic/Latino Intervention women had <=20% energy from fat at year 8.
[11] 1 (5%) Hispanic/Latino Intervention women had <=20% energy from fat at year 9.

Table 3.3 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women

Data as of: February 29, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	751	27.8	14.9	1094	27.7	15.1	0.1	0.7	0.65
FFQ Year 1	617	15.0	9.8	914	21.7	14.3	6.7	0.7	<.01
FFQ Year 2	226	14.4	8.4	304	23.1	14.2	8.7	1.1	<.01
FFQ Year 3	131	17.4	12.0	195	22.1	12.5	4.8	1.4	<.01
FFQ Year 4	163	15.7	9.9	296	21.1	12.3	5.4	1.1	<.01
FFQ Year 5	188	15.5	10.4	302	22.5	15.9	6.9	1.3	<.01
FFQ Year 6	224	15.4	9.6	393	21.8	13.0	6.4	1.0	<.01
FFQ Year 7	110	15.5	10.5	157	20.2	13.3	4.7	1.5	<.01
FFQ Year 8	45	15.1	7.5	73	19.0	9.2	3.9	1.6	0.01
FFQ Year 9	22	15.4	10.8	29	20.0	14.5	4.5	3.7	0.08
4DFR Baseline	96	19.8	7.6	134	20.9	10.0	1.1	1.2	0.57
4DFR Year 1	82	11.5	6.7	110	19.4	8.9	7.9	1.2	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	751	15.9	8.4	1094	15.7	8.2	0.2	0.4	0.48
FFQ Year 1	617	8.6	5.5	914	12.7	8.6	4.2	0.4	<.01
FFQ Year 2	226	8.7	5.3	304	13.4	8.2	4.7	0.6	<.01
FFQ Year 3	131	10.4	6.5	195	12.9	7.4	2.5	0.8	<.01
FFQ Year 4	163	9.4	5.7	296	12.4	7.1	3.1	0.6	<.01
FFQ Year 5	188	9.2	6.5	302	12.7	9.3	3.5	0.8	<.01
FFQ Year 6	224	9.3	5.7	393	12.3	7.2	3.0	0.6	<.01
FFQ Year 7	110	9.0	5.3	157	12.0	7.9	3.0	0.9	<.01
FFQ Year 8	45	8.9	4.4	73	11.3	6.8	2.4	1.1	0.04
FFQ Year 9	22	8.4	6.6	29	10.8	6.0	2.4	1.8	0.08
4DFR Baseline	96	11.5	4.6	134	13.4	6.2	1.9	0.7	0.02
4DFR Year 1	82	7.8	4.1	110	12.0	6.3	4.2	0.8	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	748	3.0	1.9	1094	2.9	1.8	0.1	0.1	0.27
FFQ Year 1	614	4.2	2.3	914	3.1	1.9	1.0	0.1	<.01
FFQ Year 2	224	4.4	2.4	304	3.2	1.7	1.2	0.2	<.01
FFQ Year 3	130	4.6	2.9	195	3.4	2.0	1.3	0.3	<.01
FFQ Year 4	163	4.7	2.7	296	3.1	2.1	1.5	0.2	<.01
FFQ Year 5	187	4.4	2.5	302	3.3	2.1	1.1	0.2	<.01
FFQ Year 6	222	4.3	2.6	393	3.1	2.0	1.2	0.2	<.01
FFQ Year 7	110	4.2	2.8	157	3.3	2.1	0.9	0.3	<.01
FFQ Year 8	45	4.5	2.4	73	3.4	2.0	1.1	0.4	0.02
FFQ Year 9	22	4.0	2.5	29	3.3	2.1	0.7	0.6	0.40
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	748	5.5	3.3	1094	5.7	3.5	0.2	0.2	0.54
FFQ Year 1	614	5.1	3.3	914	4.8	3.4	0.3	0.2	0.07
FFQ Year 2	224	5.0	3.5	304	4.9	3.1	0.0	0.3	0.48
FFQ Year 3	130	5.1	3.0	195	4.7	2.9	0.4	0.3	0.32
FFQ Year 4	163	4.3	2.9	296	4.6	2.9	0.3	0.3	0.18
FFQ Year 5	187	4.3	3.0	302	4.8	3.4	0.5	0.3	0.12
FFQ Year 6	222	4.4	3.2	393	4.4	3.1	0.1	0.3	0.86
FFQ Year 7	110	3.9	2.4	157	4.1	3.1	0.2	0.4	0.92
FFQ Year 8	45	4.2	2.4	73	4.0	2.7	0.2	0.5	0.38
FFQ Year 9	22	3.8	2.8	29	4.3	2.3	0.5	0.7	0.20

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.3 (continued)
Nutrient Intake Monitoring in White Women

Data as of: February 29, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	15871	38.7	5.0	23891	38.7	4.9	0.0	0.1	0.93
FFQ Year 1[3]	14900	24.6	7.3	22154	36.0	6.8	11.3	0.1	<.01
FFQ Year 2[4]	4836	25.8	7.5	7168	36.2	7.0	10.4	0.1	<.01
FFQ Year 3[5]	2589	27.3	7.8	3928	37.2	7.1	9.9	0.2	<.01
FFQ Year 4[6]	4206	28.2	8.0	6480	37.6	7.1	9.5	0.1	<.01
FFQ Year 5[7]	4808	28.8	8.2	7488	37.9	7.2	9.1	0.1	<.01
FFQ Year 6[8]	5306	29.4	8.3	8070	37.9	7.2	8.5	0.1	<.01
FFQ Year 7[9]	3208	30.1	8.4	5002	38.2	7.4	8.1	0.2	<.01
FFQ Year 8[10]	1533	30.4	8.5	2546	38.6	7.4	8.2	0.3	<.01
FFQ Year 9[11]	789	31.1	8.3	1185	38.9	7.6	7.8	0.4	<.01
4DFR Baseline	442	32.6	6.5	669	32.6	6.7	0.1	0.4	0.88
4DFR Year 1	405	20.4	6.7	610	32.5	6.6	12.1	0.4	<.01
Total Energy (kcal)									
FFQ Baseline	15871	1795.1	687.8	23891	1797.1	677.4	2.0	7.0	0.62
FFQ Year 1	14900	1485.6	509.0	22154	1599.0	611.4	113.4	6.1	<.01
FFQ Year 2	4836	1492.6	496.9	7168	1590.7	597.6	98.1	10.4	<.01
FFQ Year 3	2589	1484.4	511.7	3928	1583.1	618.6	98.8	14.6	<.01
FFQ Year 4	4206	1457.4	515.8	6480	1580.1	611.2	122.7	11.4	<.01
FFQ Year 5	4808	1462.8	515.8	7488	1574.3	608.2	111.6	10.6	<.01
FFQ Year 6	5306	1433.8	523.7	8070	1556.4	602.3	122.7	10.1	<.01
FFQ Year 7	3208	1422.1	528.3	5002	1554.6	617.1	132.5	13.2	<.01
FFQ Year 8	1533	1430.0	536.1	2546	1560.2	618.3	130.2	19.0	<.01
FFQ Year 9	789	1407.4	559.5	1185	1530.5	585.2	123.0	26.4	<.01
4DFR Baseline	442	1744.2	422.9	669	1740.7	447.9	3.6	26.9	0.68
4DFR Year 1	405	1461.2	331.5	610	1652.6	428.1	191.4	25.2	<.01
Total Fat (g)									
FFQ Baseline	15871	77.8	34.1	23891	77.9	33.4	0.0	0.3	0.65
FFQ Year 1	14900	40.9	20.6	22154	64.8	30.5	23.9	0.3	<.01
FFQ Year 2	4836	42.9	20.2	7168	64.9	30.1	21.9	0.5	<.01
FFQ Year 3	2589	45.3	22.5	3928	66.3	31.5	21.0	0.7	<.01
FFQ Year 4	4206	46.0	23.2	6480	67.0	31.5	21.0	0.6	<.01
FFQ Year 5	4808	47.3	23.6	7488	67.3	31.6	20.0	0.5	<.01
FFQ Year 6	5306	47.1	23.5	8070	66.5	31.2	19.4	0.5	<.01
FFQ Year 7	3208	48.1	25.1	5002	67.1	32.4	19.0	0.7	<.01
FFQ Year 8	1533	48.7	25.0	2546	67.8	32.1	19.1	1.0	<.01
FFQ Year 9	789	49.2	27.0	1185	66.8	30.6	17.7	1.3	<.01
4DFR Baseline	442	64.1	23.9	669	64.0	23.5	0.2	1.5	0.81
4DFR Year 1	405	33.0	13.0	610	60.5	22.3	27.5	1.2	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 4374 (29%) White Intervention women had <=20% energy from fat at year 1.
[4] 1099 (23%) White Intervention women had <=20% energy from fat at year 2.
[5] 482 (19%) White Intervention women had <=20% energy from fat at year 3.
[6] 671 (16%) White Intervention women had <=20% energy from fat at year 4.
[7] 682 (14%) White Intervention women had <=20% energy from fat at year 5.
[8] 605 (11%) White Intervention women had <=20% energy from fat at year 6.
[9] 339 (11%) White Intervention women had <=20% energy from fat at year 7.
[10] 169 (11%) White Intervention women had <=20% energy from fat at year 8.
[11] 56 (7%) White Intervention women had <=20% energy from fat at year 9.

Table 3.3 (continued)
Nutrient Intake Monitoring in White Women

Data as of: February 29, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	15871	27.7	13.2	23891	27.6	12.8	0.1	0.1	0.95
FFQ Year 1	14900	14.1	7.8	22154	22.9	11.6	8.8	0.1	<.01
FFQ Year 2	4836	14.7	7.5	7168	22.9	11.4	8.1	0.2	<.01
FFQ Year 3	2589	15.5	8.6	3928	23.3	12.0	7.9	0.3	<.01
FFQ Year 4	4206	15.8	8.8	6480	23.7	12.1	7.9	0.2	<.01
FFQ Year 5	4808	16.3	9.0	7488	23.8	12.1	7.5	0.2	<.01
FFQ Year 6	5306	16.2	8.8	8070	23.5	12.1	7.3	0.2	<.01
FFQ Year 7	3208	16.6	9.5	5002	23.6	12.5	7.0	0.3	<.01
FFQ Year 8	1533	16.8	9.4	2546	24.1	12.6	7.3	0.4	<.01
FFQ Year 9	789	16.9	9.9	1185	23.5	11.4	6.7	0.5	<.01
4DFR Baseline	442	21.7	9.2	669	21.6	9.1	0.1	0.6	0.64
4DFR Year 1	405	10.4	4.7	610	20.2	8.3	9.8	0.5	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	15871	15.2	7.4	23891	15.2	7.3	0.0	0.1	0.48
FFQ Year 1	14900	7.7	4.1	22154	12.4	6.4	4.7	0.1	<.01
FFQ Year 2	4836	8.1	4.1	7168	12.3	6.2	4.2	0.1	<.01
FFQ Year 3	2589	8.6	4.4	3928	12.7	6.5	4.1	0.1	<.01
FFQ Year 4	4206	8.8	4.7	6480	12.8	6.5	4.0	0.1	<.01
FFQ Year 5	4808	9.1	4.7	7488	12.9	6.6	3.8	0.1	<.01
FFQ Year 6	5306	9.1	4.8	8070	12.7	6.4	3.6	0.1	<.01
FFQ Year 7	3208	9.2	5.1	5002	12.9	6.6	3.7	0.1	<.01
FFQ Year 8	1533	9.3	5.0	2546	12.9	6.4	3.6	0.2	<.01
FFQ Year 9	789	9.5	5.5	1185	12.9	6.6	3.4	0.3	<.01
4DFR Baseline	442	12.9	5.5	669	13.2	5.7	0.3	0.3	0.51
4DFR Year 1	405	7.1	3.1	610	12.4	5.6	5.3	0.3	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	15809	3.7	1.8	23818	3.7	1.8	0.0	0.0	0.17
FFQ Year 1	14831	5.2	2.3	22079	3.9	2.0	1.2	0.0	<.01
FFQ Year 2	4817	5.2	2.3	7141	4.0	2.0	1.2	0.0	<.01
FFQ Year 3	2584	5.3	2.4	3914	4.0	2.0	1.3	0.1	<.01
FFQ Year 4	4198	5.2	2.4	6466	3.9	2.0	1.3	0.0	<.01
FFQ Year 5	4789	5.1	2.4	7463	3.9	2.1	1.2	0.0	<.01
FFQ Year 6	5286	5.0	2.4	8047	3.9	2.0	1.2	0.0	<.01
FFQ Year 7	3189	4.9	2.3	4989	3.8	2.0	1.1	0.0	<.01
FFQ Year 8	1521	4.9	2.4	2537	3.8	2.0	1.1	0.1	<.01
FFQ Year 9	781	4.8	2.4	1178	3.8	2.0	1.0	0.1	<.01
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	15807	4.7	2.4	23817	4.8	2.4	0.0	0.0	0.21
FFQ Year 1	14828	5.1	2.6	22071	4.2	2.2	0.9	0.0	<.01
FFQ Year 2	4816	5.0	2.4	7136	4.1	2.1	0.8	0.0	<.01
FFQ Year 3	2583	4.6	2.5	3909	3.9	2.1	0.7	0.1	<.01
FFQ Year 4	4194	4.4	2.3	6456	3.9	2.1	0.6	0.0	<.01
FFQ Year 5	4786	4.3	2.2	7452	3.8	2.0	0.5	0.0	<.01
FFQ Year 6	5284	4.2	2.3	8035	3.7	2.0	0.4	0.0	<.01
FFQ Year 7	3187	4.0	2.2	4981	3.7	2.0	0.3	0.0	<.01
FFQ Year 8	1521	3.9	2.2	2532	3.6	2.0	0.3	0.1	<.01
FFQ Year 9	779	3.8	2.2	1175	3.5	1.9	0.3	0.1	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.3 (continued)
Nutrient Intake Monitoring in Unknown Race/Ethnicity

Data as of: February 29, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	265	39.1	5.3	394	39.2	5.1	0.1	0.4	0.79
FFQ Year 1[3]	240	27.7	8.0	354	35.9	7.7	8.3	0.7	<.01
FFQ Year 2[4]	79	27.2	7.9	123	37.3	6.9	10.2	1.1	<.01
FFQ Year 3[5]	46	29.1	7.4	59	37.8	8.2	8.6	1.5	<.01
FFQ Year 4[6]	72	29.2	8.2	112	37.1	7.2	7.9	1.1	<.01
FFQ Year 5[7]	78	29.2	8.1	109	38.3	7.6	9.2	1.2	<.01
FFQ Year 6[8]	72	31.0	8.5	135	38.4	7.3	7.4	1.1	<.01
FFQ Year 7[9]	38	32.5	8.5	53	38.1	7.5	5.6	1.7	<.01
FFQ Year 8[10]	11	30.5	7.6	29	39.1	7.5	8.6	2.7	<.01
FFQ Year 9[11]	5	30.3	2.9	12	35.1	8.1	4.8	3.8	0.09
4DFR Baseline	17	32.2	5.5	29	32.8	5.6	0.6	1.7	0.71
4DFR Year 1	13	22.8	8.9	24	33.6	6.5	10.8	2.6	<.01
Total Energy (kcal)									
FFQ Baseline	265	1796.2	774.8	394	1726.3	769.8	70.0	61.3	0.23
FFQ Year 1	240	1505.5	628.2	354	1501.5	639.0	4.1	53.1	0.66
FFQ Year 2	79	1463.9	583.5	123	1571.6	674.2	107.8	92.3	0.33
FFQ Year 3	46	1463.7	598.3	59	1477.1	725.4	13.4	132.3	1.00
FFQ Year 4	72	1374.9	623.0	112	1495.4	657.4	120.5	97.3	0.23
FFQ Year 5	78	1459.7	553.9	109	1448.2	636.8	11.5	89.5	0.47
FFQ Year 6	72	1533.2	534.7	135	1514.7	623.9	18.4	86.8	0.50
FFQ Year 7	38	1287.5	542.8	53	1559.3	770.4	271.9	145.6	0.08
FFQ Year 8	11	1583.4	535.6	29	1350.6	510.4	232.7	183.1	0.19
FFQ Year 9	5	1400.5	467.9	12	1523.2	759.4	122.7	369.3	0.89
4DFR Baseline	17	1504.1	288.3	29	1693.4	404.8	189.3	112.0	0.10
4DFR Year 1	13	1334.5	469.5	24	1541.7	334.5	207.2	133.0	0.13
Total Fat (g)									
FFQ Baseline	265	79.0	39.4	394	75.9	38.4	3.1	3.1	0.31
FFQ Year 1	240	46.7	28.0	354	60.7	31.5	14.0	2.5	<.01
FFQ Year 2	79	44.9	29.0	123	66.7	35.1	21.8	4.7	<.01
FFQ Year 3	46	46.2	21.0	59	62.8	35.9	16.6	6.0	<.01
FFQ Year 4	72	45.7	30.4	112	63.1	33.2	17.4	4.9	<.01
FFQ Year 5	78	48.2	26.0	109	62.5	32.0	14.2	4.4	<.01
FFQ Year 6	72	53.2	26.0	135	65.0	32.4	11.8	4.4	<.01
FFQ Year 7	38	45.3	19.7	53	65.8	34.2	20.5	6.2	<.01
FFQ Year 8	11	52.6	19.4	29	60.2	27.8	7.6	9.1	0.56
FFQ Year 9	5	46.8	15.7	12	58.9	33.5	12.1	15.9	0.48
4DFR Baseline	17	54.4	16.8	29	61.8	17.4	7.4	5.2	0.18
4DFR Year 1	13	33.7	19.1	24	57.9	17.3	24.2	6.2	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 38 (16%) Unknown Intervention women had <=20% energy from fat at year 1.
[4] 16 (20%) Unknown Intervention women had <=20% energy from fat at year 2.
[5] 5 (11%) Unknown Intervention women had <=20% energy from fat at year 3.
[6] 11 (15%) Unknown Intervention women had <=20% energy from fat at year 4.
[7] 12 (15%) Unknown Intervention women had <=20% energy from fat at year 5.
[8] 8 (11%) Unknown Intervention women had <=20% energy from fat at year 6.
[9] 2 (5%) Unknown Intervention women had <=20% energy from fat at year 7.
[10] 2 (18%) Unknown Intervention women had <=20% energy from fat at year 8.
[11] 0 (0%) Unknown Intervention women had <=20% energy from fat at year 9.

Table 3.3 (continued)
Nutrient Intake Monitoring in Unknown Race/Ethnicity

Data as of: February 29, 2004

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	265	27.2	14.6	394	26.3	14.2	0.9	1.1	0.47
FFQ Year 1[3]	240	15.4	9.4	354	20.9	11.7	5.5	0.9	<.01
FFQ Year 2[4]	79	15.3	10.7	123	23.2	12.6	7.9	1.7	<.01
FFQ Year 3[5]	46	15.3	7.9	59	20.9	13.0	5.6	2.2	0.01
FFQ Year 4[6]	72	15.1	10.3	112	21.8	12.2	6.7	1.7	<.01
FFQ Year 5[7]	78	15.7	9.2	109	21.1	11.3	5.4	1.6	<.01
FFQ Year 6[8]	72	17.6	10.2	135	21.9	11.9	4.3	1.7	<.01
FFQ Year 7[9]	38	14.8	7.0	53	22.6	13.5	7.8	2.4	<.01
FFQ Year 8[10]	11	17.5	7.8	29	20.5	10.9	2.9	3.6	0.57
FFQ Year 9[11]	5	15.6	6.2	12	22.1	13.7	6.6	6.5	0.29
4DFR Baseline	17	17.6	6.7	29	21.0	7.2	3.4	2.1	0.10
4DFR Year 1	13	11.3	8.7	24	18.9	5.7	7.6	2.4	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	265	15.9	8.7	394	15.0	8.6	0.9	0.7	0.19
FFQ Year 1	240	9.0	6.0	354	11.9	6.8	2.8	0.5	<.01
FFQ Year 2	79	8.4	5.6	123	12.8	7.8	4.5	1.0	<.01
FFQ Year 3	46	9.0	4.1	59	13.1	7.9	4.1	1.3	<.01
FFQ Year 4	72	9.2	6.5	112	12.4	7.4	3.3	1.1	<.01
FFQ Year 5	78	9.8	5.4	109	12.4	7.1	2.6	1.0	0.01
FFQ Year 6	72	10.9	5.4	135	13.0	6.6	2.1	0.9	0.02
FFQ Year 7	38	9.1	4.5	53	13.0	7.3	3.9	1.3	<.01
FFQ Year 8	11	10.6	3.6	29	11.5	5.7	0.9	1.9	0.94
FFQ Year 9	5	9.2	3.6	12	10.3	4.8	1.1	2.4	0.71
4DFR Baseline	17	11.7	3.7	29	12.5	4.4	0.8	1.3	0.59
4DFR Year 1	13	6.6	3.1	24	11.8	4.3	5.2	1.4	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	264	3.7	2.0	393	3.4	2.0	0.2	0.2	0.04
FFQ Year 1	239	4.9	2.4	353	3.6	2.0	1.3	0.2	<.01
FFQ Year 2	78	5.0	2.2	123	3.9	2.3	1.1	0.3	<.01
FFQ Year 3	46	5.0	2.6	59	3.7	1.9	1.3	0.4	<.01
FFQ Year 4	71	5.0	2.7	112	4.0	2.1	1.1	0.4	0.02
FFQ Year 5	78	5.0	2.5	109	3.6	2.3	1.4	0.4	<.01
FFQ Year 6	71	5.4	2.4	135	3.9	2.2	1.5	0.3	<.01
FFQ Year 7	38	4.0	2.2	53	4.6	3.1	0.6	0.6	0.79
FFQ Year 8	11	5.6	2.7	29	3.7	2.0	1.8	0.8	0.04
FFQ Year 9	4	4.9	2.0	12	4.4	2.4	0.5	1.3	0.49
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	264	4.7	2.7	393	4.7	2.7	0.1	0.2	0.67
FFQ Year 1	239	5.0	2.9	353	4.1	2.4	0.8	0.2	<.01
FFQ Year 2	78	4.6	2.4	123	4.2	2.3	0.4	0.3	0.30
FFQ Year 3	46	4.6	3.0	59	4.1	2.8	0.5	0.6	0.38
FFQ Year 4	71	4.1	2.5	112	3.8	2.1	0.3	0.3	0.64
FFQ Year 5	78	4.5	2.3	109	3.7	2.2	0.8	0.3	<.01
FFQ Year 6	71	4.4	2.4	135	3.8	2.5	0.5	0.4	0.07
FFQ Year 7	38	3.9	2.6	53	3.4	2.0	0.5	0.5	0.47
FFQ Year 8	11	5.3	2.7	29	3.2	1.9	2.1	0.7	<.01
FFQ Year 9	4	3.8	1.4	12	3.4	2.0	0.4	1.1	0.44

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.4

Control - Intervention Difference in % Energy from Fat in WHI DM Participants
Study Subject Characteristics and Session Participation from FFQs Collected in the Last Year[1]

Data as of: February 29, 2004

	Model Including Attendance				Model Including Completion				Model Including Fat Scores			
	N	C – I (%)	R^2	(ΔR^2) for Inclusion	N	C – I (%)	R^2	(ΔR^2) for Inclusion	N	C – I (%)	R^2	(ΔR^2) for Inclusion
Demographics			16.6%				16.6%				16.6%	
Age												
60-69	6498				6498				6498			
50-54 vs. 60-69	1980	0.32			1980	0.21			1980	0.29		
55-59 vs. 60-69	3218	0.11			3218	0.05			3218	0.14		
70-79 vs. 60-69	2123	-1.18 **			2123	-0.99 *			2123	-1.04 **		
Ethnicity												
White	11402				11402				11402			
American Indian vs. White	75	2.75			75	2.87			75	3.32		
Asian/Pacific Islander vs. White	313	-0.97			313	-0.62			313	-0.95		
Black vs. White	1381	-1.72 **			1381	-1.81 **			1381	-1.45 **		
Hispanic vs. White	472	-2.74 **			472	-2.51 **			472	-2.77 **		
Unknown vs. White	176	-0.64			176	-0.50			176	-0.11		
Education												
Post H.S.	10861				10861				10861			
0-8 Years vs. Post H.S.	128	2.88			128	3.19 *			128	3.31 *		
Some H.S. or Diploma vs. Post H.S.	2830	-0.60			2830	-0.57			2830	-0.54		
Family Income												
≥75K	2515				2515				2515			
<20K vs. ≥75K	2324	-1.13 *			2324	-1.00 *			2324	-0.95		
20-35K vs. ≥75K	3270	-0.63			3270	-0.39			3270	-0.46		
35-50K vs. ≥75K	2862	-0.83			2862	-0.66			2862	-0.72		
50-75K vs. ≥75K	2848	-1.06 *			2848	-0.99 *			2848	-1.10 *		
HRT Randomized												
No	11607				11607				11607			
Yes vs. No	2212	-0.07			2212	-0.14			2212	-0.05		
Visit			16.8%	(0.2%)			16.8%	(0.2%)			16.8%	(0.2%)
Visit Year												
AV-6	4338				4338				4338			
AV-5 vs. AV-6	643	-0.86			643	-1.16 *			643	-0.77		
AV-7 vs. AV-6	3938	-0.53			3938	-0.48			3938	-0.51		
AV-8 vs. AV-6	2719	-0.35			2719	-0.31			2719	-0.37		
AV-9 vs. AV-6	2171	3.17 **			2171	4.87 **			2171	3.20 **		
Clinic Effect			22.2%	(5.4%)			22.2%	(5.4%)			22.2%	(5.4%)
Intervention Participation												
# Sessions Attended in Previous 12 Months			25.9%	(3.7%)								
None	11031											
1 vs. None	637	5.07 **										
2 vs. None	819	6.19 **										
3 vs. None	813	6.80 **										
4+ vs. None	519	7.25 **										
# Sessions Completed in Previous 12 Months							25.8%	(3.6%)				
None					10201							
1 vs. None					347	3.09 **						
2 vs. None					674	5.86 **						
3 vs. None					955	6.90 **						
4+ vs. None					1642	8.23 **						
# Fat Scores Provided in Previous 12 Months											26.9%	(4.7%)
None									11145			
1 vs. None									518	4.12 **		
2 vs. None									581	5.65 **		
3 vs. None									683	7.54 **		
4+ vs. None									892	8.49 **		

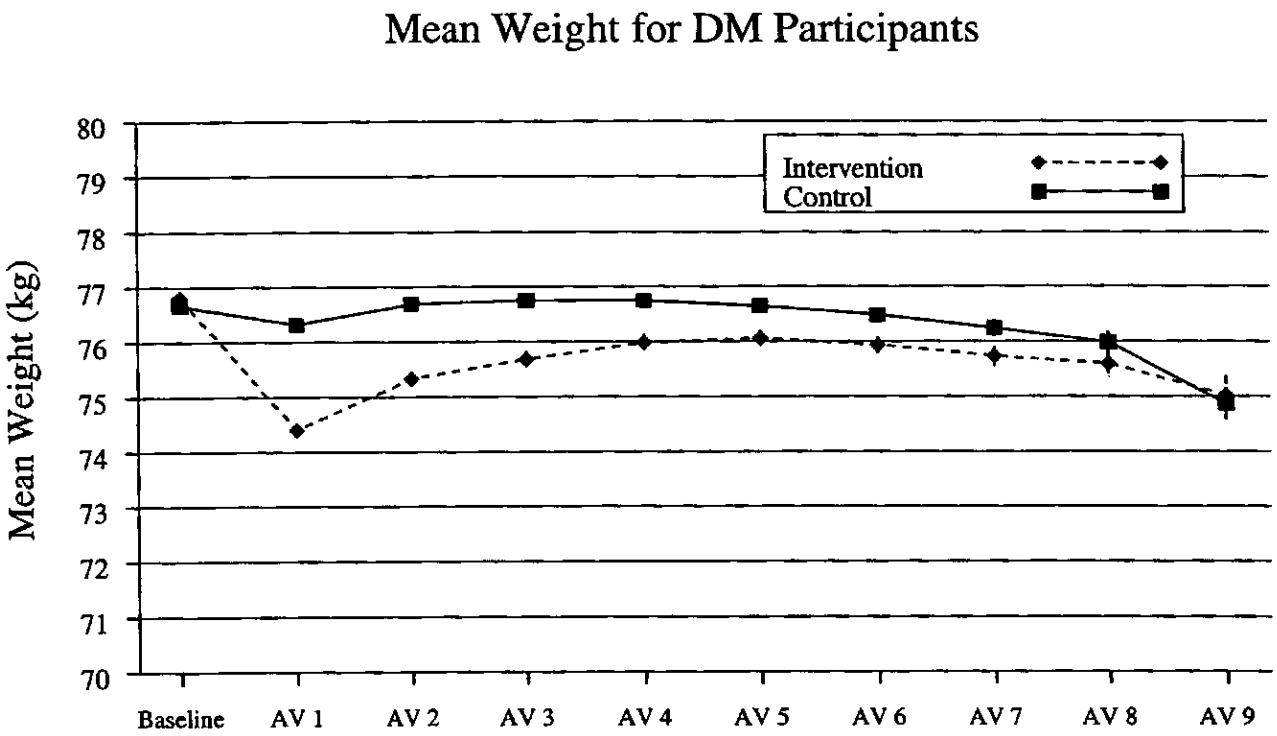
[1] Model adjusted for clinic effects.

* P-value <0.05 from a two-sided test.

**P-value <0.01 from a two-sided test.

Figure 3.2
Mean Body Weight for DM Participants
Stratified by Treatment Arm

Data as of: February 29, 2004



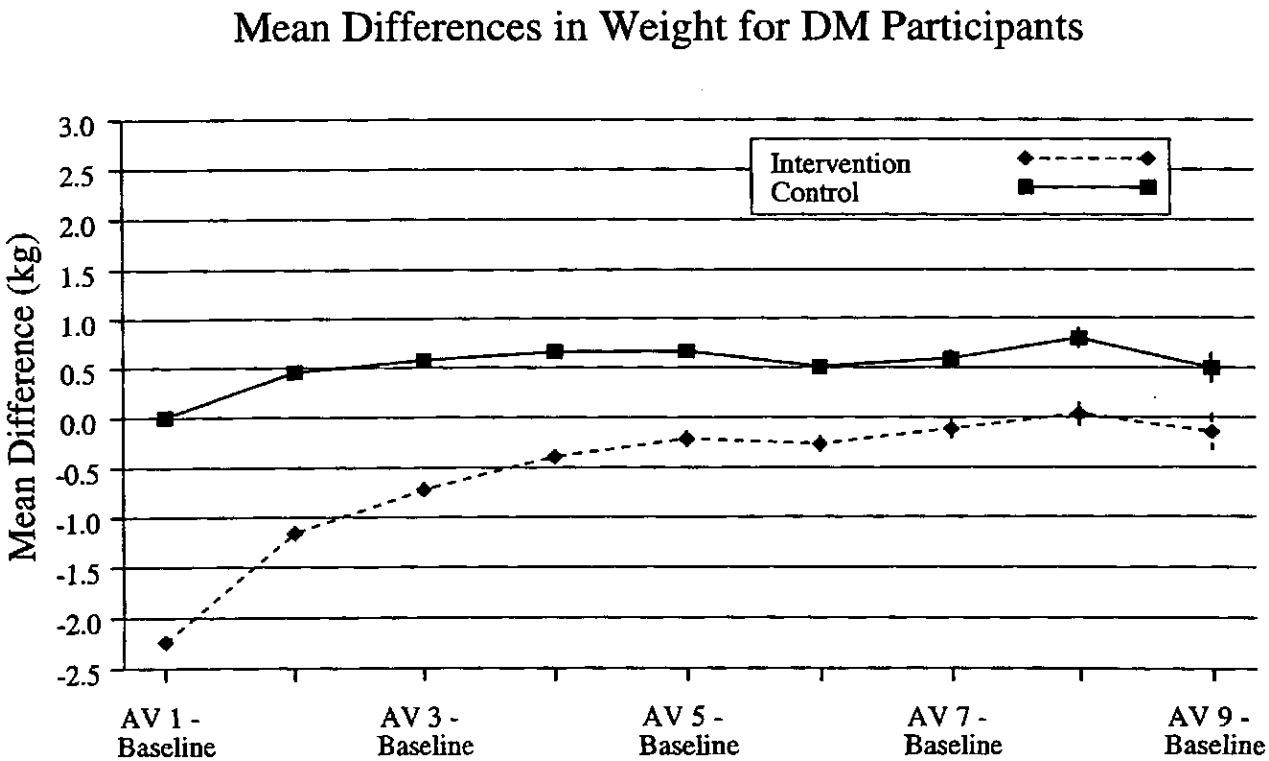


Table 3.5
Reasons for Stopping DM[1]

Data as of: February 29, 2004

Reasons[2]	(N = 2736)	
Personal/family		
Demands of work	232	8.5%
Family illness, emergency, or other family demands[3]	275	10.1%
Financial problems	9	0.3%
Lack of cooperation/support from family/friends[4]	49	1.8%
Living in nursing home	29	1.1%
Issues of interest in study[5]	258	9.4%
Travel		
Too far to CC	116	4.2%
Moved out of area or refuses to be followed at another CC	27	1.0%
Other travel issues[6]	63	2.3%
Visits & Procedures		
Doesn't like visits/calls	55	2.0%
Doesn't like required forms or safety procedures[7]	46	1.7%
Problems with other procedures[8]	12	0.4%
Worried about health effects of medical tests/procedures	3	0.1%
Wants test results[9]	1	< 0.1%
Problems with the CC[10]	29	1.1%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted DM Intervention.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Family illness, emergency or other family demands," "Death in the family or of a close friend," and "Caregiver responsibilities demanding time, effort, lifestyle changes."
[4] Combines "Lack of cooperation/support from family and/or friends" and "Family/friends request that she withdraw."
[5] Combines "Conflicting priorities other than work or family," "Feels discouraged regarding participation overall," "Loss of interest, boredom," "Feels it is not an important study," and "In another study in conflict with WHI intervention."
[6] Combines "Transportation problems (other than distance)," "Traffic," "Parking at CC," and "CC neighborhood/safety."
[7] Combines "Doesn't like filling out forms (other than those required for safety)", and "Doesn't like required safety forms and/or procedures".
[8] Combines "Doesn't like mammograms," "Cost of mammograms," "Doesn't like having blood drawn", "Doesn't like ECG," "Doesn't like gynecologic procedures," and "Doesn't like other procedures (other than those required for safety)."
[9] Combines "Wants results of blood analyses," and "Wants results of bone mineral density measurement."
[10] Combines "Problem with the CC," "Problem with CC staff person (other than DM Group Nutritionist)," and "Staff change/turnover."

Table 3.5 (continued)
Reasons for Stopping DM[1]

Data as of: February 29, 2004

Reasons[2]	(N = 2736)	
Symptoms		
GI problems[3]	3	0.1%
Hair/skin changes	1	< 0.1%
Weight loss/gain	5	0.2%
HRT related symptoms[4]	4	0.1%
Other[5]	8	0.3%
Health Conditions		
Disease and/or health conditions[6]	110	4.0%
Communication difficulties[7]	75	2.7%
Intervention		
Doesn't like randomized nature of intervention	12	0.4%
Expected some benefit from intervention	32	1.2%
Feels guilty/unhappy or like a failure for not meeting study goals	20	0.7%
Pill issues[8]	7	0.3%
CaD issues[9]	1	< 0.1%
HRT issues[10]	2	< 0.1%
Problem with DM group nutritionist or group members	30	1.1%
Doesn't like attending DM intervention classes	70	2.6%
Doesn't like self-monitoring	49	1.8%
Doesn't like budgeting fat grams	9	0.3%
Health concerns regarding long-term risk/benefits of low fat diet	24	0.9%
Unhappy that not losing weight	21	0.8%
Not in control of meal preparation	16	0.6%
Too difficult to meet or maintain dietary goals	53	1.9%
Doesn't like eating low fat diet	36	1.3%
Doesn't like eating 5 vegetables/fruits per day	2	< 0.1%
Doesn't like eating 6 grains per day	8	0.3%
Feels fat gram goal is unrealistic	8	0.3%
Eating pattern conflicts with personal health beliefs	32	1.2%
Other Health Issues		
Worried about costs if adverse effects occur	1	< 0.1%
Expected more health care	14	0.5%
Advised not to participate by health care provider[11]	21	0.8%
Study conflicts with other health issues[12]	30	1.1%
Other		
Other reasons not listed above	515	18.8%
Refuses to give a reason	100	3.7%

[1] Does not include reasons reported by women who stopped and later restarted DM Intervention.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Bloating/Gas," "Constipation," and "Other gastrointestinal problems."
[4] Combines "Vaginal bleeding," "Breast tenderness," "Other breast changes," "Vaginal changes (e.g., dryness)," and "Hot flashes/night sweats."
[5] Combines "Headaches," "Low energy/too tired," "Possible allergic reaction," and "Other symptoms not listed above."
[6] Combines "Breast cancer," "Complex or atypical hyperplasia," "Endometrial cancer," "Deep vein thrombosis," "Pulmonary embolism," "Gallbladder disease," "Hypercalcemia," "Kidney failure/dialysis," "Renal calculi," "High triglycerides (> 1000 mg/dl) ," "Malignant melanoma," "Meningioma," "Heart attack," "Stroke," "Arthritis," "Diabetes," "Depression," "Cholesterol (high or concern about levels)," "Osteoporosis," and "Other health conditions not listed above."
[7] Combines "Communication problem," "Loss of vision and/or hearing," and "Cognitive/memory changes."
[8] Combines "Doesn't like taking pills," "Doesn't like taste of pills," "Unable to swallow pills," and "Takes too many pills."
[9] Combines "Wants to take her own calcium," "Feels diet is already sufficient in calcium/Vitamin D," "Taking more than the maximum allowable IU of Vit D," and "Taking Calcitriol."
[10] Combines "Has made a personal decision to go on active HRT," "Has made a personal decision that she does not want to be on HRT," "Advised to go on active HRT by health care provider," "Advised to not be on active HRT by health care provider," "Has made a personal decision to go on SERM (e.g., Evista/raloxifene, tamoxifen)," "Advised to go on SERM (e.g., Evista/raloxifene, tamoxifen) by health care provider," and "Taking testosterone medications."
[11] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason."
[12] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues."

Table 3.6
Reasons for Stopping DM by Age at Screening and Race/Ethnicity[1]

Data as of: February 29, 2004

	Age at Screening									
	All (N = 19,541)		50 – 54 (N = 2,784)		55 – 59 (N = 4,422)		60 – 69 (N = 9,085)		70 – 79 (N = 3,250)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping Intervention	2736	14.0%	434	15.6%	579	13.1%	1117	12.3%	606	18.6%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	275	10.1%	44	10.1%	74	12.8%	108	9.7%	49	8.1%
Demands of work	232	8.5%	76	17.5%	71	12.3%	69	6.2%	16	2.6%
Issues of interest in study[6]	258	9.4%	41	9.4%	59	10.2%	108	9.7%	50	8.3%
Too far to CC	116	4.2%	22	5.1%	33	5.7%	42	3.8%	19	3.1%
Other ("Other reasons not listed above")	515	18.8%	95	21.9%	135	23.3%	197	17.6%	88	14.5%

	Race/Ethnicity											
	American Indian/ Alaskan (N = 88)		Asian/Pacific Islander (N = 431)		Black/African American (N = 2,135)		Hispanic/Latino (N = 751)		White (N = 15,871)		Unknown (N = 265)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping Intervention	23	26.1%	107	24.8%	360	16.9%	171	22.8%	2017	12.7%	58	21.9%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	2	8.7%	5	4.7%	31	8.6%	20	11.7%	212	10.5%	5	8.6%
Demands of work	1	4.3%	6	5.6%	45	12.5%	16	9.4%	160	7.9%	4	6.9%
Issues of interest in study[6]	3	13.0%	8	7.5%	38	10.6%	7	4.1%	199	9.9%	3	5.2%
Too far to CC	2	8.7%	3	2.8%	6	1.7%	5	2.9%	99	4.9%	1	1.7%
Other ("Other reasons not listed above")	5	21.7%	46	43.0%	49	13.6%	49	28.7%	350	17.4%	16	27.6%

[1] Does not include reasons reported by women who stopped and later restarted DM intervention.
[2] Percentages are of DM intervention participants in the same age or race/ethnicity category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of DM intervention participants in the same age or race/ethnicity category who stopped DM intervention.
[5] Combines "Family illness, emergency or other family demands," "Death in the family or of a close friend," and "Caregiver responsibilities demanding time, effort, lifestyle changes."
[6] Combines "Conflicting priorities other than work or family," "Feels discouraged regarding participation overall," "Loss of interest, boredom," "Feels it is not an important study," and "In another study in conflict with WHI intervention."

Table 3.7
Blood Specimen Analysis: DM Participants

Data as of: February 29, 2004

	N	Mean[1]	S.D.[1]
Micronutrients			
Alpha-Carotene (μg/ml)			
Baseline	2731	0.08	0.08
AV-1	2500	0.08	0.07
AV-3	2204	0.07	0.07
AV-6	848	0.07	0.07
AV-1 – Baseline	2425	0.00	0.06
AV-3 – Baseline	2133	-0.01	0.07
AV-6 – Baseline	817	-0.01	0.07
Beta-Carotene (μg/ml)			
Baseline	2731	0.30	0.28
AV-1	2500	0.30	0.29
AV-3	2204	0.29	0.29
AV-6	848	0.31	0.31
AV-1 – Baseline	2425	0.00	0.22
AV-3 – Baseline	2133	-0.00	0.26
AV-6 – Baseline	817	0.02	0.31
Alpha-tocopherol (μg/ml)			
Baseline	2731	16.28	7.30
AV-1	2500	16.95	7.52
AV-3	2204	18.19	7.71
AV-6	848	19.05	8.72
AV-1 – Baseline	2425	0.76	5.49
AV-3 – Baseline	2133	1.91	6.76
AV-6 – Baseline	817	3.63	7.92
Gamma-tocopherol (μg/ml)			
Baseline	2731	2.21	1.42
AV-1	2499	1.85	1.31
AV-3	2204	1.68	1.32
AV-6	848	1.67	1.35
AV-1 – Baseline	2424	-0.36	0.92
AV-3 – Baseline	2133	-0.54	1.13
AV-6 – Baseline	817	-0.60	1.28
Beta-Cryptoxanthine (μg/ml)			
Baseline	2731	0.09	0.07
AV-1	2499	0.09	0.07
AV-3	2204	0.10	0.08
AV-6	848	0.10	0.09
AV-1 – Baseline	2424	0.00	0.06
AV-3 – Baseline	2133	0.01	0.07
AV-6 – Baseline	817	0.02	0.08
Lycopene (μg/ml)			
Baseline	2731	0.41	0.19
AV-1	2500	0.41	0.19
AV-3	2204	0.38	0.20
AV-6	848	0.37	0.20
AV-1 – Baseline	2425	-0.01	0.16
AV-3 – Baseline	2133	-0.03	0.20
AV-6 – Baseline	817	-0.03	0.21

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 3.7 (continued)
Blood Specimen Analysis: DM Participants

Data as of: February 29, 2004

	N	Mean[1]	S.D.[1]
Lutein and Zeaxanthin (μg/ml)			
Baseline	2731	0.21	0.10
AV-1	2500	0.22	0.10
AV-3	2204	0.20	0.10
AV-6	848	0.19	0.10
AV-1 – Baseline	2425	0.00	0.07
AV-3 – Baseline	2133	-0.02	0.08
AV-6 – Baseline	817	-0.03	0.09
Retinol (μg/ml)			
Baseline	2731	0.61	0.15
AV-1	2500	0.62	0.15
AV-3	2204	0.61	0.15
AV-6	848	0.64	0.16
AV-1 – Baseline	2425	0.00	0.10
AV-3 – Baseline	2133	-0.00	0.13
AV-6 – Baseline	817	0.04	0.14
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	2640	130.69	32.41
AV-1	2398	130.70	32.64
AV-3	2108	131.99	33.20
AV-6	825	121.25	30.73
AV-1 – Baseline	2275	-0.23	22.36
AV-3 – Baseline	1982	0.53	28.14
AV-6 – Baseline	787	-6.74	27.19
Factor VII C (%)[2]			
Baseline	2595	129.82	30.74
AV-1	2367	127.30	30.37
AV-3	2099	130.98	33.84
AV-6	822	135.90	35.10
AV-1 – Baseline	2211	-2.82	22.49
AV-3 – Baseline	1936	0.77	28.23
AV-6 – Baseline	767	3.61	30.04
Fibrinogen (mg/dl)			
Baseline	2630	299.80	60.77
AV-1	2391	297.58	60.63
AV-3	2109	289.34	59.25
AV-6	827	284.62	57.69
AV-1 – Baseline	2264	-2.56	49.77
AV-3 – Baseline	1975	-10.52	52.49
AV-6 – Baseline	788	-13.31	55.08
Hormones/Other			
Glucose (mg/dl)			
Baseline	2729	100.17	26.76
AV-1	2492	98.81	26.23
AV-3	2230	99.26	26.63
AV-6	851	97.50	21.98
AV-1 – Baseline	2417	-1.34	18.98
AV-3 – Baseline	2157	-1.07	20.95
AV-6 – Baseline	819	-0.62	18.78

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.
[2] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.7 (continued)
Blood Specimen Analysis: DM Participants

Data as of: February 29, 2004

	N	Mean[1]	S.D.[1]
Insulin (μIU/ml)			
Baseline	2661	11.69	8.77
AV-1	2430	11.30	10.33
AV-3	2127	12.76	10.04
AV-6	848	10.12	14.56
AV-1 – Baseline	2319	-0.31	8.54
AV-3 – Baseline	2009	1.03	8.44
AV-6 – Baseline	811	-0.87	6.65
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	2730	157.45	86.55
AV-1	2498	159.31	86.45
AV-3	2230	160.27	89.36
AV-6	850	158.08	85.85
AV-1 – Baseline	2423	2.51	54.98
AV-3 – Baseline	2157	1.94	74.02
AV-6 – Baseline	819	2.96	70.31
Total Cholesterol (mg/dl)			
Baseline	2730	224.13	38.13
AV-1	2498	217.41	37.33
AV-3	2230	215.58	35.64
AV-6	850	214.19	36.19
AV-1 – Baseline	2423	-6.61	26.66
AV-3 – Baseline	2157	-8.17	31.96
AV-6 – Baseline	819	-10.22	34.98
LDL-C (mg/dl)			
Baseline	2680	133.82	35.18
AV-1	2453	126.48	34.05
AV-3	2192	125.51	33.66
AV-6	835	125.12	33.51
AV-1 – Baseline	2359	-6.91	23.78
AV-3 – Baseline	2092	-7.52	29.26
AV-6 – Baseline	795	-8.24	32.30

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 3.7 (continued)
Blood Specimen Analysis: DM Participants

Data as of: February 29, 2004

	N	Mean[1]	S.D.[1]
HDL-C (mg/dl)			
Baseline	2722	59.05	15.68
AV-1	2496	59.28	15.30
AV-3	2226	58.74	15.63
AV-6	849	58.35	14.78
AV-1 – Baseline	2415	-0.08	8.79
AV-3 – Baseline	2147	-0.42	9.89
AV-6 – Baseline	816	-1.92	10.73
HDL-2 (mg/dl)			
Baseline	2662	18.29	8.17
AV-1	2455	18.85	8.36
AV-3	2198	16.44	6.63
AV-6	848	16.75	6.40
AV-1 – Baseline	2329	0.31	4.97
AV-3 – Baseline	2079	-1.92	5.62
AV-6 – Baseline	801	-1.48	6.02
HDL-3 (mg/dl)			
Baseline	2664	40.86	9.05
AV-1	2456	40.47	8.58
AV-3	2198	42.18	9.77
AV-6	848	41.60	9.48
AV-1 – Baseline	2332	-0.51	5.55
AV-3 – Baseline	2081	1.41	6.93
AV-6 – Baseline	802	-0.44	7.69
Lp(a) (mg/dl)			
Baseline	2693	25.96	26.14
AV-1	2465	25.11	25.93
AV-3	2166	23.23	23.36
AV-6	845	31.82	26.74
AV-1 – Baseline	2366	-0.66	10.22
AV-3 – Baseline	2075	-2.34	13.78
AV-6 – Baseline	803	7.89	17.76

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 3.8
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: February 29, 2004

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (μg/ml)			
Baseline	74	0.05	0.04
AV-1	58	0.06	0.05
AV-3	46	0.05	0.03
AV-6	4	0.04	0.03
AV-1 – Baseline	57	0.01	0.04
AV-3 – Baseline	45	-0.01	0.03
AV-6 – Baseline	4	-0.02	0.02
Beta-Carotene (μg/ml)			
Baseline	74	0.25	0.24
AV-1	58	0.27	0.31
AV-3	46	0.21	0.15
AV-6	4	0.13	0.08
AV-1 – Baseline	57	0.00	0.20
AV-3 – Baseline	45	-0.05	0.19
AV-6 – Baseline	4	-0.02	0.03
Alpha-tocopherol (μg/ml)			
Baseline	74	18.18	10.41
AV-1	58	18.10	9.60
AV-3	46	16.54	6.33
AV-6	4	20.34	17.41
AV-1 – Baseline	57	1.00	5.58
AV-3 – Baseline	45	-1.65	9.06
AV-6 – Baseline	4	7.42	16.80
Gamma-tocopherol (μg/ml)			
Baseline	74	2.20	1.27
AV-1	58	1.80	1.22
AV-3	46	1.83	1.15
AV-6	4	2.06	1.05
AV-1 – Baseline	57	-0.41	0.84
AV-3 – Baseline	45	-0.34	1.02
AV-6 – Baseline	4	-0.97	1.26
Beta-Cryptoxanthine (μg/ml)			
Baseline	74	0.07	0.04
AV-1	58	0.07	0.04
AV-3	46	0.08	0.04
AV-6	4	0.07	0.05
AV-1 – Baseline	57	0.01	0.04
AV-3 – Baseline	45	0.02	0.03
AV-6 – Baseline	4	0.03	0.03
Lycopene (μg/ml)			
Baseline	74	0.36	0.17
AV-1	58	0.35	0.16
AV-3	46	0.31	0.18
AV-6	4	0.33	0.18
AV-1 – Baseline	57	0.00	0.13
AV-3 – Baseline	45	-0.05	0.19
AV-6 – Baseline	4	0.01	0.13

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: February 29, 2004

	N	Mean	S.D.
Lutein and Zeaxanthin (µg/ml)			
Baseline	74	0.20	0.13
AV-1	58	0.20	0.10
AV-3	46	0.17	0.08
AV-6	4	0.14	0.09
AV-1 – Baseline	57	0.00	0.06
AV-3 – Baseline	45	-0.01	0.05
AV-6 – Baseline	4	-0.06	0.09
Retinol (µg/ml)			
Baseline	74	0.61	0.15
AV-1	58	0.60	0.16
AV-3	46	0.56	0.13
AV-6	4	0.61	0.24
AV-1 – Baseline	57	-0.01	0.08
AV-3 – Baseline	45	-0.04	0.13
AV-6 – Baseline	4	-0.06	0.18
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	71	136.94	31.58
AV-1	56	138.29	30.70
AV-3	47	136.51	32.79
AV-6	4	124.00	27.93
AV-1 – Baseline	54	0.72	18.41
AV-3 – Baseline	45	-2.58	27.89
AV-6 – Baseline	4	-9.75	26.70
Factor VII C (%)[1]			
Baseline	71	131.42	29.79
AV-1	56	127.55	26.77
AV-3	47	133.11	34.87
AV-6	4	147.50	34.39
AV-1 – Baseline	54	-2.04	14.64
AV-3 – Baseline	45	2.24	22.78
AV-6 – Baseline	4	16.00	22.89
Fibrinogen (mg/dl)			
Baseline	71	305.41	66.58
AV-1	56	312.86	75.90
AV-3	47	297.96	61.48
AV-6	4	294.50	53.97
AV-1 – Baseline	54	4.89	54.99
AV-3 – Baseline	45	-9.80	40.66
AV-6 – Baseline	4	-35.75	46.59
Hormones/Other			
Glucose (mg/dl)			
Baseline	74	105.54	33.02
AV-1	58	102.17	21.11
AV-3	48	105.75	27.80
AV-6	4	148.50	54.46
AV-1 – Baseline	57	-3.11	17.66
AV-3 – Baseline	47	-0.09	37.17
AV-6 – Baseline	4	30.75	46.18

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.8 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: February 29, 2004

	N	Mean	S.D.
Insulin (μIU/ml)			
Baseline	69	13.31	7.90
AV-1	56	12.09	6.16
AV-3	43	14.67	9.79
AV-6	4	14.75	11.39
AV-1 – Baseline	52	-1.10	4.70
AV-3 – Baseline	39	2.48	8.12
AV-6 – Baseline	4	-3.70	6.14
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	73	183.51	91.72
AV-1	57	170.98	88.64
AV-3	48	171.71	97.12
AV-6	4	173.75	105.23
AV-1 – Baseline	55	-1.87	52.17
AV-3 – Baseline	46	-15.70	72.47
AV-6 – Baseline	3	-15.33	77.15
Total Cholesterol (mg/dl)			
Baseline	73	218.42	34.36
AV-1	57	210.86	36.96
AV-3	48	204.35	38.05
AV-6	4	195.75	27.66
AV-1 – Baseline	55	-7.84	23.63
AV-3 – Baseline	46	-13.30	29.00
AV-6 – Baseline	3	-22.67	12.86
LDL-C (mg/dl)			
Baseline	71	127.08	33.42
AV-1	54	123.00	33.59
AV-3	46	117.13	37.18
AV-6	4	105.75	43.25
AV-1 – Baseline	52	-5.42	20.42
AV-3 – Baseline	44	-9.82	26.94
AV-6 – Baseline	3	-22.00	13.11
HDL-C (mg/dl)			
Baseline	73	55.62	15.88
AV-1	57	56.05	15.58
AV-3	48	55.00	13.69
AV-6	4	55.50	17.25
AV-1 – Baseline	55	-0.07	7.51
AV-3 – Baseline	46	0.24	7.32
AV-6 – Baseline	3	2.67	1.15
HDL-2 (mg/dl)			
Baseline	70	16.94	8.07
AV-1	56	17.41	7.86
AV-3	47	15.60	5.22
AV-6	4	13.25	6.70
AV-1 – Baseline	52	0.27	4.41
AV-3 – Baseline	43	-1.37	4.26
AV-6 – Baseline	3	0.00	5.00

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: February 29, 2004

	N	Mean	S.D.
HDL-3 (mg/dl)			
Baseline	71	38.83	8.31
AV-1	56	38.21	8.59
AV-3	47	40.02	8.54
AV-6	4	42.25	10.90
AV-1 – Baseline	53	-0.25	5.01
AV-3 – Baseline	44	1.73	5.50
AV-6 – Baseline	4	2.25	4.27
Lp(a) (mg/dl)			
Baseline	71	21.48	20.85
AV-1	56	20.38	19.84
AV-3	46	17.67	16.27
AV-6	4	23.50	1.73
AV-1 – Baseline	54	0.69	9.69
AV-3 – Baseline	43	-3.95	12.22
AV-6 – Baseline	4	5.00	6.78

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: February 29, 2004

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	194	0.10	0.10
AV-1	176	0.10	0.10
AV-3	170	0.09	0.09
AV-6	46	0.08	0.07
AV-1 – Baseline	174	-0.00	0.10
AV-3 – Baseline	168	-0.02	0.09
AV-6 – Baseline	46	-0.01	0.11
Beta-Carotene (µg/ml)			
Baseline	194	0.44	0.42
AV-1	176	0.48	0.53
AV-3	170	0.45	0.58
AV-6	46	0.46	0.47
AV-1 – Baseline	174	0.05	0.40
AV-3 – Baseline	168	0.01	0.45
AV-6 – Baseline	46	0.03	0.54
Alpha-tocopherol (µg/ml)			
Baseline	194	19.35	9.96
AV-1	176	19.48	11.01
AV-3	170	21.93	11.34
AV-6	46	23.91	11.76
AV-1 – Baseline	174	0.34	6.81
AV-3 – Baseline	168	2.79	9.63
AV-6 – Baseline	46	6.73	11.42
Gamma-tocopherol (µg/ml)			
Baseline	194	1.68	1.18
AV-1	176	1.30	0.98
AV-3	170	1.15	0.88
AV-6	46	1.13	0.83
AV-1 – Baseline	174	-0.38	0.85
AV-3 – Baseline	168	-0.53	0.89
AV-6 – Baseline	46	-0.60	1.08
Beta-Cryptoxanthine (µg/ml)			
Baseline	194	0.18	0.17
AV-1	176	0.19	0.18
AV-3	170	0.21	0.22
AV-6	46	0.26	0.22
AV-1 – Baseline	174	0.01	0.14
AV-3 – Baseline	168	0.03	0.18
AV-6 – Baseline	46	0.12	0.19
Lycopene (µg/ml)			
Baseline	194	0.38	0.21
AV-1	176	0.37	0.19
AV-3	170	0.33	0.22
AV-6	46	0.34	0.19
AV-1 – Baseline	174	-0.02	0.18
AV-3 – Baseline	168	-0.05	0.22
AV-6 – Baseline	46	-0.00	0.20

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: February 29, 2004

	N	Mean	S.D.
Lutein and Zeaxanthin (µg/ml)			
Baseline	194	0.27	0.12
AV-1	176	0.28	0.12
AV-3	170	0.25	0.12
AV-6	46	0.23	0.11
AV-1 – Baseline	174	0.01	0.09
AV-3 – Baseline	168	-0.02	0.09
AV-6 – Baseline	46	-0.01	0.13
Retinol (µg/ml)			
Baseline	194	0.61	0.14
AV-1	176	0.62	0.15
AV-3	170	0.62	0.14
AV-6	46	0.65	0.12
AV-1 – Baseline	174	0.01	0.09
AV-3 – Baseline	168	0.01	0.12
AV-6 – Baseline	46	0.06	0.12
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	188	130.96	29.85
AV-1	167	130.84	29.26
AV-3	161	134.88	32.04
AV-6	46	127.35	27.17
AV-1 – Baseline	161	-0.96	20.48
AV-3 – Baseline	156	2.15	28.13
AV-6 – Baseline	46	-3.30	22.28
Factor VII C (%)[1]			
Baseline	188	126.67	24.61
AV-1	167	126.11	26.33
AV-3	161	133.47	30.84
AV-6	46	139.89	32.33
AV-1 – Baseline	161	-1.03	18.59
AV-3 – Baseline	156	5.26	24.20
AV-6 – Baseline	45	14.18	23.68
Fibrinogen (mg/dl)			
Baseline	189	290.03	57.67
AV-1	167	284.84	57.04
AV-3	162	275.60	57.26
AV-6	46	277.85	48.30
AV-1 – Baseline	162	-6.69	53.11
AV-3 – Baseline	158	-11.63	52.70
AV-6 – Baseline	46	-19.46	57.19
Hormones/Other			
Glucose (mg/dl)			
Baseline	194	99.77	18.15
AV-1	176	100.55	23.78
AV-3	172	101.98	21.35
AV-6	46	103.00	29.58
AV-1 – Baseline	174	0.29	19.27
AV-3 – Baseline	170	1.66	14.19
AV-6 – Baseline	46	6.87	29.08

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.8 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: February 29, 2004

	N	Mean	S.D.
Insulin (μIU/ml)			
Baseline	188	10.24	5.58
AV-1	168	10.02	5.92
AV-3	163	11.64	6.03
AV-6	46	8.79	5.82
AV-1 – Baseline	164	-0.28	3.78
AV-3 – Baseline	157	1.04	5.55
AV-6 – Baseline	46	-1.04	4.53
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	193	171.96	92.30
AV-1	176	172.70	94.01
AV-3	172	189.97	208.28
AV-6	46	193.43	91.69
AV-1 – Baseline	173	0.05	60.11
AV-3 – Baseline	169	17.79	194.02
AV-6 – Baseline	46	27.20	80.85
Total Cholesterol (mg/dl)			
Baseline	193	219.75	35.95
AV-1	176	213.29	33.31
AV-3	172	209.40	35.11
AV-6	46	205.07	31.53
AV-1 – Baseline	173	-7.59	24.36
AV-3 – Baseline	169	-8.49	28.58
AV-6 – Baseline	46	-14.65	36.08
LDL-C (mg/dl)			
Baseline	186	127.87	34.91
AV-1	170	120.72	30.18
AV-3	166	116.84	31.76
AV-6	45	108.36	27.51
AV-1 – Baseline	164	-8.60	25.08
AV-3 – Baseline	160	-8.84	26.71
AV-6 – Baseline	45	-19.29	34.30
HDL-C (mg/dl)			
Baseline	193	58.23	13.48
AV-1	176	59.91	14.05
AV-3	172	57.93	13.91
AV-6	46	57.72	13.18
AV-1 – Baseline	173	1.27	8.38
AV-3 – Baseline	169	-0.78	9.58
AV-6 – Baseline	46	-0.26	10.46
HDL-2 (mg/dl)			
Baseline	189	18.05	7.21
AV-1	174	19.51	7.32
AV-3	170	15.99	5.41
AV-6	46	16.20	5.08
AV-1 – Baseline	168	1.10	4.53
AV-3 – Baseline	163	-2.41	5.08
AV-6 – Baseline	45	-1.53	6.40

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: February 29, 2004

	N	Mean	S.D.
HDL-3 (mg/dl)			
Baseline	189	40.39	8.00
AV-1	174	40.50	8.34
AV-3	170	41.89	9.23
AV-6	46	41.52	9.60
AV-1 – Baseline	168	0.17	5.36
AV-3 – Baseline	163	1.44	7.25
AV-6 – Baseline	45	0.82	8.84
Lp(a) (mg/dl)			
Baseline	190	18.31	16.20
AV-1	175	16.41	14.04
AV-3	168	14.45	12.05
AV-6	46	24.87	15.43
AV-1 – Baseline	170	-2.14	12.79
AV-3 – Baseline	162	-3.54	10.05
AV-6 – Baseline	45	4.67	15.45

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: February 29, 2004

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (μg/ml)			
Baseline	778	0.06	0.08
AV-1	695	0.07	0.07
AV-3	576	0.06	0.06
AV-6	191	0.06	0.08
AV-1 – Baseline	673	0.00	0.06
AV-3 – Baseline	556	-0.01	0.05
AV-6 – Baseline	181	-0.00	0.07
Beta-Carotene (μg/ml)			
Baseline	778	0.31	0.34
AV-1	695	0.32	0.30
AV-3	576	0.31	0.35
AV-6	191	0.29	0.26
AV-1 – Baseline	673	0.00	0.22
AV-3 – Baseline	556	0.01	0.28
AV-6 – Baseline	181	0.02	0.22
Alpha-tocopherol (μg/ml)			
Baseline	778	13.95	6.04
AV-1	695	14.54	6.11
AV-3	576	15.23	6.65
AV-6	191	14.46	5.90
AV-1 – Baseline	673	0.48	4.71
AV-3 – Baseline	556	1.34	5.83
AV-6 – Baseline	181	1.24	5.60
Gamma-tocopherol (μg/ml)			
Baseline	778	2.54	1.35
AV-1	695	2.27	1.31
AV-3	576	2.10	1.31
AV-6	191	2.22	1.36
AV-1 – Baseline	673	-0.20	0.90
AV-3 – Baseline	556	-0.42	1.07
AV-6 – Baseline	181	-0.39	1.16
Beta-Cryptoxanthine (μg/ml)			
Baseline	778	0.09	0.06
AV-1	695	0.09	0.06
AV-3	576	0.09	0.07
AV-6	191	0.10	0.06
AV-1 – Baseline	673	-0.00	0.06
AV-3 – Baseline	556	0.01	0.06
AV-6 – Baseline	181	0.01	0.05
Lycopene (μg/ml)			
Baseline	778	0.40	0.21
AV-1	695	0.38	0.20
AV-3	576	0.36	0.21
AV-6	191	0.36	0.21
AV-1 – Baseline	673	-0.01	0.19
AV-3 – Baseline	556	-0.03	0.22
AV-6 – Baseline	181	-0.02	0.20

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: February 29, 2004

	N	Mean	S.D.
Lutein and Zeaxanthin (μg/ml)			
Baseline	778	0.23	0.11
AV-1	695	0.24	0.11
AV-3	576	0.22	0.10
AV-6	191	0.21	0.11
AV-1 – Baseline	673	0.01	0.08
AV-3 – Baseline	556	-0.01	0.09
AV-6 – Baseline	181	-0.03	0.10
Retinol (μg/ml)			
Baseline	778	0.55	0.15
AV-1	695	0.55	0.14
AV-3	576	0.56	0.16
AV-6	191	0.58	0.14
AV-1 – Baseline	673	0.01	0.09
AV-3 – Baseline	556	0.01	0.12
AV-6 – Baseline	181	0.05	0.13
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	750	114.89	27.06
AV-1	676	115.58	27.54
AV-3	553	119.00	29.10
AV-6	185	110.10	26.32
AV-1 – Baseline	634	1.01	20.62
AV-3 – Baseline	517	3.47	25.56
AV-6 – Baseline	171	-1.82	23.12
Factor VII C (%)[1]			
Baseline	730	118.33	30.11
AV-1	664	116.39	26.78
AV-3	550	119.82	30.10
AV-6	186	126.56	30.73
AV-1 – Baseline	609	-1.90	21.05
AV-3 – Baseline	497	0.82	27.62
AV-6 – Baseline	165	7.10	32.00
Fibrinogen (mg/dl)			
Baseline	748	321.11	66.58
AV-1	676	319.65	66.81
AV-3	552	309.78	66.20
AV-6	186	314.76	69.26
AV-1 – Baseline	635	-3.57	49.22
AV-3 – Baseline	515	-14.67	58.00
AV-6 – Baseline	171	-5.81	59.81
Hormones/Other			
Glucose (mg/dl)			
Baseline	778	106.88	37.04
AV-1	692	106.95	38.23
AV-3	587	105.35	34.44
AV-6	194	104.54	30.07
AV-1 – Baseline	670	0.65	26.79
AV-3 – Baseline	566	-1.25	28.27
AV-6 – Baseline	184	0.50	31.86

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.8 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: February 29, 2004

	N	Mean	S.D.
Insulin (μIU/ml)			
Baseline	766	14.32	17.77
AV-1	685	13.94	10.92
AV-3	566	15.66	18.39
AV-6	194	15.86	40.00
AV-1 – Baseline	657	-0.24	6.18
AV-3 – Baseline	540	0.50	14.47
AV-6 – Baseline	183	0.19	12.72
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	778	119.73	53.08
AV-1	695	118.85	48.13
AV-3	587	120.68	52.28
AV-6	194	118.51	46.04
AV-1 – Baseline	673	0.62	36.51
AV-3 – Baseline	566	1.27	42.95
AV-6 – Baseline	184	-4.30	46.47
Total Cholesterol (mg/dl)			
Baseline	778	220.25	41.98
AV-1	695	216.26	41.44
AV-3	587	210.30	39.53
AV-6	194	209.17	32.94
AV-1 – Baseline	673	-3.45	25.93
AV-3 – Baseline	566	-9.22	30.50
AV-6 – Baseline	184	-11.92	37.10
LDL-C (mg/dl)			
Baseline	777	137.81	39.42
AV-1	694	132.73	39.32
AV-3	586	127.73	37.17
AV-6	194	126.86	30.43
AV-1 – Baseline	671	-4.55	24.27
AV-3 – Baseline	564	-9.46	29.59
AV-6 – Baseline	184	-10.44	34.99
HDL-C (mg/dl)			
Baseline	777	58.50	15.06
AV-1	695	59.80	15.03
AV-3	586	58.48	14.42
AV-6	194	58.58	14.31
AV-1 – Baseline	672	0.98	8.16
AV-3 – Baseline	564	-0.02	9.07
AV-6 – Baseline	184	-0.65	10.64
HDL-2 (mg/dl)			
Baseline	766	18.30	7.83
AV-1	688	19.38	8.63
AV-3	580	16.25	5.78
AV-6	193	16.15	5.91
AV-1 – Baseline	657	0.79	4.96
AV-3 – Baseline	554	-1.99	5.42
AV-6 – Baseline	181	-2.30	6.42

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: February 29, 2004

	N	Mean	S.D.
HDL-3 (mg/dl)			
Baseline	766	40.18	8.64
AV-1	688	40.36	8.03
AV-3	580	42.26	9.55
AV-6	193	42.47	9.34
AV-1 – Baseline	657	0.11	5.17
AV-3 – Baseline	554	1.99	6.40
AV-6 – Baseline	181	1.57	7.72
Lp(a) (mg/dl)			
Baseline	766	38.57	27.55
AV-1	690	37.92	28.01
AV-3	571	34.62	24.52
AV-6	192	43.30	23.61
AV-1 – Baseline	660	-0.06	11.97
AV-3 – Baseline	545	-2.91	18.51
AV-6 – Baseline	179	12.31	17.21

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: February 29, 2004

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (μg/ml)			
Baseline	304	0.09	0.10
AV-1	268	0.09	0.07
AV-3	235	0.07	0.07
AV-6	62	0.07	0.05
AV-1 – Baseline	261	-0.00	0.10
AV-3 – Baseline	228	-0.02	0.11
AV-6 – Baseline	59	-0.01	0.04
Beta-Carotene (μg/ml)			
Baseline	304	0.30	0.41
AV-1	268	0.28	0.27
AV-3	235	0.26	0.26
AV-6	62	0.26	0.22
AV-1 – Baseline	261	-0.01	0.35
AV-3 – Baseline	228	-0.06	0.37
AV-6 – Baseline	59	-0.01	0.35
Alpha-tocopherol (μg/ml)			
Baseline	304	15.99	7.06
AV-1	268	17.01	7.71
AV-3	235	17.23	7.46
AV-6	62	22.00	13.28
AV-1 – Baseline	261	1.26	5.94
AV-3 – Baseline	228	0.87	6.75
AV-6 – Baseline	59	5.85	9.16
Gamma-tocopherol (μg/ml)			
Baseline	304	2.12	1.35
AV-1	268	1.89	1.40
AV-3	235	1.85	1.37
AV-6	62	1.69	1.22
AV-1 – Baseline	261	-0.25	0.94
AV-3 – Baseline	228	-0.31	1.06
AV-6 – Baseline	59	-0.50	1.01
Beta-Cryptoxanthine (μg/ml)			
Baseline	304	0.11	0.10
AV-1	268	0.11	0.09
AV-3	235	0.11	0.09
AV-6	62	0.12	0.09
AV-1 – Baseline	261	-0.01	0.09
AV-3 – Baseline	228	0.00	0.09
AV-6 – Baseline	59	0.00	0.10
Lycopene (μg/ml)			
Baseline	304	0.43	0.21
AV-1	268	0.41	0.19
AV-3	235	0.39	0.20
AV-6	62	0.42	0.21
AV-1 – Baseline	261	-0.02	0.16
AV-3 – Baseline	228	-0.04	0.19
AV-6 – Baseline	59	0.01	0.23

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: February 29, 2004

	N	Mean	S.D.
Lutein and Zeaxanthin (µg/ml)			
Baseline	304	0.20	0.10
AV-1	268	0.20	0.10
AV-3	235	0.19	0.08
AV-6	62	0.17	0.08
AV-1 – Baseline	261	-0.00	0.08
AV-3 – Baseline	228	-0.01	0.07
AV-6 – Baseline	59	-0.01	0.07
Retinol (µg/ml)			
Baseline	304	0.55	0.13
AV-1	268	0.57	0.13
AV-3	235	0.57	0.14
AV-6	62	0.59	0.15
AV-1 – Baseline	261	0.02	0.09
AV-3 – Baseline	228	0.00	0.10
AV-6 – Baseline	59	0.05	0.14
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	292	123.52	27.45
AV-1	254	124.28	28.84
AV-3	231	127.79	31.84
AV-6	60	119.82	23.54
AV-1 – Baseline	241	2.02	21.59
AV-3 – Baseline	220	3.56	26.68
AV-6 – Baseline	56	-1.20	20.38
Factor VII C (%)[1]			
Baseline	285	123.49	28.28
AV-1	244	121.88	27.43
AV-3	229	126.73	31.96
AV-6	59	139.41	31.35
AV-1 – Baseline	229	0.34	21.10
AV-3 – Baseline	213	3.05	27.33
AV-6 – Baseline	52	8.67	24.40
Fibrinogen (mg/dl)			
Baseline	291	305.49	65.72
AV-1	253	309.02	70.72
AV-3	231	293.99	63.57
AV-6	60	300.95	65.94
AV-1 – Baseline	240	-0.18	55.83
AV-3 – Baseline	219	-10.59	52.71
AV-6 – Baseline	56	-11.02	61.85
Hormones/Other			
Glucose (mg/dl)			
Baseline	303	101.84	32.88
AV-1	267	105.04	35.37
AV-3	239	107.39	38.08
AV-6	62	106.52	33.07
AV-1 – Baseline	259	1.56	20.97
AV-3 – Baseline	231	2.20	19.28
AV-6 – Baseline	59	4.32	24.36

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.8 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: February 29, 2004

	N	Mean	S.D.
Insulin (μIU/ml)			
Baseline	295	13.48	8.60
AV-1	264	13.29	11.77
AV-3	227	13.93	8.12
AV-6	62	13.41	9.48
AV-1 – Baseline	252	-0.41	8.83
AV-3 – Baseline	215	0.48	6.72
AV-6 – Baseline	58	-0.38	8.09
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	304	162.20	74.64
AV-1	268	165.55	76.95
AV-3	239	177.77	102.49
AV-6	62	192.11	107.09
AV-1 – Baseline	261	2.52	54.45
AV-3 – Baseline	232	11.30	78.27
AV-6 – Baseline	59	11.61	77.72
Total Cholesterol (mg/dl)			
Baseline	304	217.42	34.74
AV-1	268	211.75	35.63
AV-3	239	212.58	36.00
AV-6	62	214.23	37.34
AV-1 – Baseline	261	-4.50	25.14
AV-3 – Baseline	232	-4.44	30.01
AV-6 – Baseline	59	-7.17	35.61
LDL-C (mg/dl)			
Baseline	299	130.02	32.07
AV-1	263	124.25	33.22
AV-3	230	123.69	32.88
AV-6	60	124.22	34.01
AV-1 – Baseline	254	-5.89	22.66
AV-3 – Baseline	220	-5.94	27.71
AV-6 – Baseline	56	-7.41	31.28
HDL-C (mg/dl)			
Baseline	304	55.16	13.69
AV-1	268	55.39	12.67
AV-3	238	55.06	14.19
AV-6	62	52.87	11.76
AV-1 – Baseline	261	1.38	7.92
AV-3 – Baseline	231	0.36	8.95
AV-6 – Baseline	59	-0.54	9.08
HDL-2 (mg/dl)			
Baseline	299	16.27	6.53
AV-1	265	16.84	6.84
AV-3	236	15.26	5.81
AV-6	62	14.24	5.23
AV-1 – Baseline	256	0.79	4.83
AV-3 – Baseline	225	-1.04	5.48
AV-6 – Baseline	58	-1.05	6.24

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: February 29, 2004

HDL-3 (mg/dl)			
Baseline	299	38.53	8.03
AV-1	265	38.54	7.60
AV-3	236	39.69	9.09
AV-6	62	38.63	8.19
AV-1 – Baseline	256	0.67	5.16
AV-3 – Baseline	225	1.35	6.17
AV-6 – Baseline	58	0.64	6.16
Lp(a) (mg/dl)			
Baseline	303	20.75	22.48
AV-1	264	19.30	19.99
AV-3	233	19.71	21.44
AV-6	61	27.56	21.89
AV-1 – Baseline	257	-1.04	7.88
AV-3 – Baseline	226	-1.27	11.34
AV-6 – Baseline	58	8.02	11.76

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: White Women

Data as of: February 29, 2004

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (μg/ml)			
Baseline	1327	0.08	0.08
AV-1	1255	0.08	0.07
AV-3	1138	0.07	0.07
AV-6	533	0.07	0.07
AV-1 – Baseline	1212	0.00	0.06
AV-3 – Baseline	1098	-0.01	0.07
AV-6 – Baseline	515	-0.01	0.07
Beta-Carotene (μg/ml)			
Baseline	1327	0.29	0.26
AV-1	1255	0.30	0.27
AV-3	1138	0.28	0.26
AV-6	533	0.31	0.31
AV-1 – Baseline	1212	0.01	0.21
AV-3 – Baseline	1098	-0.00	0.25
AV-6 – Baseline	515	0.02	0.31
Alpha-tocopherol (μg/ml)			
Baseline	1327	16.46	7.23
AV-1	1255	17.16	7.43
AV-3	1138	18.51	7.59
AV-6	533	19.32	8.31
AV-1 – Baseline	1212	0.79	5.50
AV-3 – Baseline	1098	2.05	6.71
AV-6 – Baseline	515	3.73	7.81
Gamma-tocopherol (μg/ml)			
Baseline	1327	2.19	1.43
AV-1	1254	1.82	1.31
AV-3	1138	1.63	1.31
AV-6	533	1.61	1.35
AV-1 – Baseline	1211	-0.39	0.93
AV-3 – Baseline	1098	-0.57	1.15
AV-6 – Baseline	515	-0.64	1.31
Beta-Cryptoxanthine (μg/ml)			
Baseline	1327	0.08	0.06
AV-1	1254	0.09	0.07
AV-3	1138	0.09	0.07
AV-6	533	0.10	0.08
AV-1 – Baseline	1211	0.00	0.05
AV-3 – Baseline	1098	0.01	0.06
AV-6 – Baseline	515	0.02	0.07
Lycopene (μg/ml)			
Baseline	1327	0.41	0.19
AV-1	1255	0.41	0.19
AV-3	1138	0.39	0.20
AV-6	533	0.37	0.20
AV-1 – Baseline	1212	-0.01	0.16
AV-3 – Baseline	1098	-0.03	0.20
AV-6 – Baseline	515	-0.03	0.21

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: White Women

Data as of: February 29, 2004

	N	Mean	S.D.
Lutein and Zeaxanthin (μg/ml)			
Baseline	1327	0.21	0.10
AV-1	1255	0.21	0.10
AV-3	1138	0.19	0.10
AV-6	533	0.18	0.09
AV-1 – Baseline	1212	0.00	0.07
AV-3 – Baseline	1098	-0.02	0.08
AV-6 – Baseline	515	-0.03	0.09
Retinol (μg/ml)			
Baseline	1327	0.63	0.15
AV-1	1255	0.63	0.15
AV-3	1138	0.62	0.15
AV-6	533	0.65	0.16
AV-1 – Baseline	1212	0.00	0.10
AV-3 – Baseline	1098	-0.01	0.13
AV-6 – Baseline	515	0.03	0.14
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	1285	133.03	32.74
AV-1	1199	132.97	32.99
AV-3	1080	133.75	33.43
AV-6	518	122.61	31.22
AV-1 – Baseline	1139	-0.47	22.67
AV-3 – Baseline	1009	-0.03	28.40
AV-6 – Baseline	498	-7.55	27.52
Factor VII C (%)[1]			
Baseline	1267	131.72	30.77
AV-1	1191	129.05	30.81
AV-3	1076	132.54	34.20
AV-6	515	136.73	35.38
AV-1 – Baseline	1113	-3.18	22.90
AV-3 – Baseline	990	0.48	28.44
AV-6 – Baseline	489	2.61	29.68
Fibrinogen (mg/dl)			
Baseline	1277	297.02	59.14
AV-1	1193	294.43	58.41
AV-3	1081	287.00	57.58
AV-6	519	280.43	54.65
AV-1 – Baseline	1127	-2.46	49.42
AV-3 – Baseline	1003	-9.87	51.89
AV-6 – Baseline	499	-14.08	54.09
Hormones/Other			
Glucose (mg/dl)			
Baseline	1326	99.21	24.82
AV-1	1251	97.36	23.57
AV-3	1145	97.88	24.58
AV-6	533	95.75	18.89
AV-1 – Baseline	1209	-1.79	17.66
AV-3 – Baseline	1105	-1.38	19.80
AV-6 – Baseline	514	-1.39	15.06

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.8 (continued)
Blood Specimen Analysis: White Women

Data as of: February 29, 2004

	N	Mean	S.D.
Insulin (μIU/ml)			
Baseline	1289	11.31	6.90
AV-1	1209	10.90	10.28
AV-3	1091	12.36	8.60
AV-6	530	9.24	6.80
AV-1 – Baseline	1146	-0.32	8.94
AV-3 – Baseline	1022	1.09	7.54
AV-6 – Baseline	508	-1.04	5.38
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	1329	161.16	88.95
AV-1	1255	163.56	89.10
AV-3	1145	163.25	84.34
AV-6	532	159.59	85.67
AV-1 – Baseline	1214	2.93	56.73
AV-3 – Baseline	1106	1.21	69.56
AV-6 – Baseline	515	2.69	71.28
Total Cholesterol (mg/dl)			
Baseline	1329	225.13	37.82
AV-1	1255	217.95	36.96
AV-3	1145	216.64	34.99
AV-6	532	215.24	36.73
AV-1 – Baseline	1214	-7.11	26.89
AV-3 – Baseline	1106	-8.22	32.33
AV-6 – Baseline	515	-10.02	34.70
LDL-C (mg/dl)			
Baseline	1296	133.76	34.74
AV-1	1225	125.95	33.38
AV-3	1125	125.64	33.19
AV-6	521	125.66	33.95
AV-1 – Baseline	1173	-7.27	23.73
AV-3 – Baseline	1067	-7.34	29.36
AV-6 – Baseline	496	-7.69	31.94
HDL-C (mg/dl)			
Baseline	1322	59.37	15.86
AV-1	1253	59.41	15.46
AV-3	1143	59.01	15.87
AV-6	531	58.64	15.00
AV-1 – Baseline	1207	-0.33	8.91
AV-3 – Baseline	1099	-0.52	10.06
AV-6 – Baseline	512	-2.21	10.81
HDL-2 (mg/dl)			
Baseline	1285	18.40	8.27
AV-1	1225	18.86	8.40
AV-3	1126	16.53	6.80
AV-6	531	16.99	6.53
AV-1 – Baseline	1149	0.20	4.97
AV-3 – Baseline	1056	-1.94	5.66
AV-6 – Baseline	502	-1.38	5.92

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: White Women

Data as of: February 29, 2004

	N	Mean	S.D.
HDL-3 (mg/dl)			
Baseline	1286	41.11	9.18
AV-1	1226	40.60	8.70
AV-3	1126	42.32	9.84
AV-6	531	41.65	9.53
AV-1 – Baseline	1151	-0.68	5.61
AV-3 – Baseline	1057	1.33	7.02
AV-6 – Baseline	502	-0.80	7.67
Lp(a) (mg/dl)			
Baseline	1309	24.94	25.94
AV-1	1234	24.15	25.81
AV-3	1110	22.33	23.23
AV-6	530	30.94	27.40
AV-1 – Baseline	1179	-0.68	10.00
AV-3 – Baseline	1062	-2.26	13.12
AV-6 – Baseline	505	7.39	18.11

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: Unknown Women

Data as of: February 29, 2004

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (μg/ml)			
Baseline	54	0.08	0.08
AV-1	48	0.08	0.08
AV-3	39	0.08	0.09
AV-6	12	0.04	0.03
AV-1 – Baseline	48	0.00	0.06
AV-3 – Baseline	38	-0.00	0.06
AV-6 – Baseline	12	-0.00	0.03
Beta-Carotene (μg/ml)			
Baseline	54	0.27	0.22
AV-1	48	0.27	0.21
AV-3	39	0.30	0.26
AV-6	12	0.26	0.21
AV-1 – Baseline	48	0.01	0.13
AV-3 – Baseline	38	0.03	0.24
AV-6 – Baseline	12	0.02	0.22
Alpha-tocopherol (μg/ml)			
Baseline	54	17.31	9.14
AV-1	48	17.12	9.40
AV-3	39	17.79	8.85
AV-6	12	16.85	9.80
AV-1 – Baseline	48	-0.32	6.54
AV-3 – Baseline	38	0.22	6.04
AV-6 – Baseline	12	-0.44	9.59
Gamma-tocopherol (μg/ml)			
Baseline	54	2.14	1.16
AV-1	48	2.01	1.05
AV-3	39	2.08	1.37
AV-6	12	2.42	1.78
AV-1 – Baseline	48	-0.11	0.76
AV-3 – Baseline	38	0.03	0.90
AV-6 – Baseline	12	0.13	1.27
Beta-Cryptoxanthine (μg/ml)			
Baseline	54	0.11	0.11
AV-1	48	0.10	0.06
AV-3	39	0.13	0.20
AV-6	12	0.11	0.11
AV-1 – Baseline	48	-0.01	0.08
AV-3 – Baseline	38	0.02	0.18
AV-6 – Baseline	12	0.01	0.10
Lycopene (μg/ml)			
Baseline	54	0.41	0.20
AV-1	48	0.40	0.20
AV-3	39	0.33	0.16
AV-6	12	0.33	0.13
AV-1 – Baseline	48	-0.01	0.18
AV-3 – Baseline	38	-0.06	0.19
AV-6 – Baseline	12	-0.13	0.21

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: Unknown Women

Data as of: February 29, 2004

	N	Mean	S.D.
Lutein and Zeaxanthin (μg/ml)			
Baseline	54	0.22	0.12
AV-1	48	0.23	0.16
AV-3	39	0.22	0.12
AV-6	12	0.22	0.10
AV-1 – Baseline	48	0.01	0.10
AV-3 – Baseline	38	-0.01	0.08
AV-6 – Baseline	12	-0.05	0.09
Retinol (μg/ml)			
Baseline	54	0.60	0.19
AV-1	48	0.59	0.15
AV-3	39	0.59	0.11
AV-6	12	0.65	0.19
AV-1 – Baseline	48	0.00	0.11
AV-3 – Baseline	38	-0.00	0.14
AV-6 – Baseline	12	-0.04	0.19
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	54	122.80	29.36
AV-1	46	117.07	27.58
AV-3	36	126.72	28.80
AV-6	12	109.25	46.71
AV-1 – Baseline	46	-2.28	24.54
AV-3 – Baseline	35	1.57	38.77
AV-6 – Baseline	12	-29.58	58.21
Factor VII C (%)[1]			
Baseline	54	124.19	29.15
AV-1	45	120.33	24.54
AV-3	36	126.22	29.80
AV-6	12	134.17	63.53
AV-1 – Baseline	45	0.24	21.75
AV-3 – Baseline	35	1.37	36.22
AV-6 – Baseline	12	-8.67	62.19
Fibrinogen (mg/dl)			
Baseline	54	303.07	65.04
AV-1	46	299.48	64.12
AV-3	36	275.89	55.49
AV-6	12	260.50	51.94
AV-1 – Baseline	46	-8.85	39.70
AV-3 – Baseline	35	-23.20	38.92
AV-6 – Baseline	12	-12.17	38.96
Hormones/Other			
Glucose (mg/dl)			
Baseline	54	98.13	24.54
AV-1	48	100.52	25.50
AV-3	39	104.79	35.30
AV-6	12	100.33	18.94
AV-1 – Baseline	48	0.63	11.85
AV-3 – Baseline	38	7.42	29.42
AV-6 – Baseline	12	-0.92	22.25

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.8 (continued)
Blood Specimen Analysis: Unknown Women

Data as of: February 29, 2004

	N	Mean	S.D.
Insulin (μIU/ml)			
Baseline	54	10.05	5.84
AV-1	48	10.77	5.60
AV-3	37	12.60	6.78
AV-6	12	12.71	9.78
AV-1 – Baseline	48	0.44	3.29
AV-3 – Baseline	36	3.19	4.98
AV-6 – Baseline	12	1.42	6.58
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	53	164.81	100.03
AV-1	47	156.70	77.06
AV-3	39	161.46	72.04
AV-6	12	195.00	146.97
AV-1 – Baseline	47	-5.06	60.23
AV-3 – Baseline	38	-3.47	66.79
AV-6 – Baseline	12	-9.67	111.18
Total Cholesterol (mg/dl)			
Baseline	53	227.85	36.95
AV-1	47	228.19	34.97
AV-3	39	225.15	36.55
AV-6	12	211.67	18.53
AV-1 – Baseline	47	-2.96	26.93
AV-3 – Baseline	38	-0.89	33.35
AV-6 – Baseline	12	-5.17	28.85
LDL-C (mg/dl)			
Baseline	51	135.41	35.38
AV-1	47	135.53	34.62
AV-3	39	132.08	35.25
AV-6	11	122.00	19.71
AV-1 – Baseline	45	-1.62	24.69
AV-3 – Baseline	37	-1.22	32.20
AV-6 – Baseline	11	6.55	17.22
HDL-C (mg/dl)			
Baseline	53	59.77	16.73
AV-1	47	61.23	15.74
AV-3	39	60.72	17.62
AV-6	12	57.67	13.14
AV-1 – Baseline	47	0.81	9.88
AV-3 – Baseline	38	0.66	10.08
AV-6 – Baseline	12	-4.00	11.82
HDL-2 (mg/dl)			
Baseline	53	19.72	10.47
AV-1	47	20.62	10.35
AV-3	39	18.08	7.92
AV-6	12	16.17	5.70
AV-1 – Baseline	47	0.38	6.46
AV-3 – Baseline	38	-2.00	7.00
AV-6 – Baseline	12	-3.50	7.48

(continues)

Table 3.8 (continued)
Blood Specimen Analysis: Unknown Women

Data as of: February 29, 2004

HDL-3 (mg/dl)			
Baseline	53	40.06	7.72
AV-1	47	40.62	7.03
AV-3	39	42.64	10.51
AV-6	12	41.50	9.38
AV-1 – Baseline	47	0.43	6.08
AV-3 – Baseline	38	2.66	6.89
AV-6 – Baseline	12	-0.50	8.02
Lp(a) (mg/dl)			
Baseline	54	23.89	29.23
AV-1	46	21.20	20.78
AV-3	38	21.32	20.01
AV-6	12	26.08	16.92
AV-1 – Baseline	46	-0.57	9.08
AV-3 – Baseline	37	-3.38	28.81
AV-6 – Baseline	12	15.25	16.00

Table 3.9
Bone Mineral Density[1] Analysis: DM Participants

Data as of: February 29, 2004[2]

	N	Mean	S.D.
Whole Body Scan			
Baseline	3621	1.03	0.11
AV1	3277	1.03	0.11
AV3	3101	1.04	0.11
AV6	2769	1.05	0.12
AV9	741	1.06	0.14
AV1 % Change from baseline BMD[3]	3248	0.18	2.50
AV3 % Change from baseline BMD[3]	3073	1.30	3.62
AV6 % Change from baseline BMD[3]	2741	2.10	5.33
AV9 % Change from baseline BMD[3]	709	2.62	6.71
Spine Scan			
Baseline	3510	0.99	0.17
AV1	3177	1.00	0.17
AV3	3017	1.01	0.17
AV6	2675	1.02	0.18
AV9	701	0.99	0.17
AV1 % Change from baseline BMD[3]	3156	0.74	3.82
AV3 % Change from baseline BMD[3]	2992	2.13	5.21
AV6 % Change from baseline BMD[3]	2655	3.29	6.89
AV9 % Change from baseline BMD[3]	672	3.08	8.04
Hip Scan			
Baseline	3620	0.87	0.14
AV1	3275	0.87	0.14
AV3	3099	0.88	0.14
AV6	2795	0.88	0.14
AV9	732	0.85	0.14
AV1 % Change from baseline BMD[3]	3254	-0.04	2.76
AV3 % Change from baseline BMD[3]	3071	0.98	4.18
AV6 % Change from baseline BMD[3]	2763	0.18	5.26
AV9 % Change from baseline BMD[3]	700	-1.07	6.27

[1] Measured in (g/cm^2).
[2] Because of technical problems, data from Birmingham are based on scans collected through October 2003 only.
[3] AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x100.

Table 3.10
Bone Mineral Density[1] Analysis: DM Participants by Race/Ethnicity

Data as of: February 29, 2004[2]

	Black/African American			Hispanic/Latino			White		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan									
Baseline	583	1.08	0.11	195	1.05	0.11	2786	1.01	0.11
AV1	513	1.09	0.11	152	1.05	0.11	2569	1.01	0.10
AV3	496	1.10	0.12	152	1.05	0.12	2411	1.03	0.11
AV6	440	1.09	0.12	148	1.09	0.14	2136	1.04	0.12
AV9	37	1.11	0.12	45	1.10	0.18	650	1.05	0.14
AV1 % Change from baseline BMD[3]	507	0.98	2.96	151	-0.33	2.24	2548	0.06	2.38
AV3 % Change from baseline BMD[3]	491	2.02	2.94	151	0.65	4.45	2390	1.20	3.68
AV6 % Change from baseline BMD[3]	434	0.41	3.41	148	4.39	7.55	2115	2.28	5.38
AV9 % Change from baseline BMD[3]	35	0.43	6.27	45	4.99	8.27	620	2.57	6.59
Spine Scan									
Baseline	576	1.07	0.18	188	0.97	0.15	2689	0.97	0.16
AV1	506	1.08	0.18	146	0.98	0.16	2482	0.98	0.16
AV3	491	1.09	0.19	147	0.96	0.15	2337	1.00	0.17
AV6	413	1.10	0.19	145	0.98	0.16	2072	1.01	0.17
AV9	37	1.09	0.18	43	0.95	0.16	612	0.99	0.17
AV1 % Change from baseline BMD[3]	501	0.80	4.31	145	0.15	4.38	2468	0.75	3.66
AV3 % Change from baseline BMD[3]	487	2.10	5.25	146	0.08	5.92	2318	2.29	5.13
AV6 % Change from baseline BMD[3]	408	2.15	6.75	145	1.01	6.98	2058	3.70	6.87
AV9 % Change from baseline BMD[3]	35	-0.72	7.47	43	1.74	7.90	585	3.44	8.00
Hip Scan									
Baseline	584	0.97	0.15	195	0.88	0.14	2784	0.85	0.13
AV1	514	0.98	0.15	152	0.88	0.14	2566	0.85	0.13
AV3	496	0.99	0.15	152	0.88	0.14	2409	0.86	0.13
AV6	446	0.96	0.15	150	0.89	0.14	2154	0.86	0.13
AV9	37	0.93	0.14	45	0.87	0.14	641	0.85	0.13
AV1 % Change from baseline BMD[3]	510	0.84	2.87	151	-0.62	2.94	2551	-0.18	2.67
AV3 % Change from baseline BMD[3]	492	1.40	3.83	150	0.79	5.76	2388	0.90	4.10
AV6 % Change from baseline BMD[3]	440	-1.43	4.74	148	1.80	6.14	2131	0.40	5.19
AV9 % Change from baseline BMD[3]	35	-4.14	7.21	44	-0.25	5.87	613	-0.97	6.16

[1] Measured in (g/cm^2).
[2] Because of technical problems, data from Birmingham are based on scans collected through October 2003 only.
[3] AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x100.

Table 3.11
Lost-to-Follow-up and Vital Status: DM Participants

Data as of: February 29, 2004

	DM Participants (N = 48,835)	
	N	%
Vital Status/Participation		
Deceased	1873	3.8
Alive: Current Participation[1]	44400	90.9
Alive: Recent Participation[2]	626	1.3
Alive: Past/Unknown Participation[3]	28	0.1
Stopped Follow-Up[4]	1252	2.6
Lost to Follow-Up[5]	656	1.3

[1] Participants who have filled in a Form 33 within the last 9 months.
[2] Participants who last filled in a Form 33 between 9 and 18 months ago.
[3] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 3.12
Verified Outcomes (Annualized Percentages) by Age for Dietary Modification

Data as of: February 29, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11039	22715	8120
Mean follow-up (months)	84.6	91.3	87.3	82.6	81.1
Cancer					
Breast cancer	1821 (0.53%)	215 (0.41%)	409 (0.51%)	868 (0.56%)	329 (0.60%)
Invasive breast cancer	1456 (0.42%)	156 (0.29%)	332 (0.41%)	703 (0.45%)	265 (0.48%)
Non-invasive breast cancer	376 (0.11%)	61 (0.12%)	79 (0.10%)	169 (0.11%)	67 (0.12%)
Ovarian cancer	149 (0.04%)	16 (0.03%)	31 (0.04%)	67 (0.04%)	35 (0.06%)
Endometrial cancer[1]	250 (0.07%)	27 (0.05%)	56 (0.07%)	120 (0.08%)	47 (0.09%)
Colorectal cancer	436 (0.13%)	27 (0.05%)	72 (0.09%)	220 (0.14%)	117 (0.21%)
Other cancer[2]	1684 (0.49%)	147 (0.28%)	287 (0.36%)	846 (0.54%)	404 (0.74%)
Total cancer	4177 (1.21%)	418 (0.79%)	822 (1.02%)	2037 (1.30%)	900 (1.64%)
Cardiovascular					
CHD[3]	1127 (0.33%)	60 (0.11%)	132 (0.16%)	534 (0.34%)	401 (0.73%)
CHD death[4]	278 (0.08%)	13 (0.02%)	24 (0.03%)	123 (0.08%)	118 (0.22%)
Total MI[5]	942 (0.27%)	48 (0.09%)	114 (0.14%)	453 (0.29%)	327 (0.60%)
Clinical MI	892 (0.26%)	41 (0.08%)	108 (0.13%)	432 (0.28%)	311 (0.57%)
Evolving Q-wave MI[6]	52 (0.02%)	7 (0.01%)	6 (0.01%)	23 (0.01%)	16 (0.03%)
Possible evolving Q-wave MI[6]	219 (0.06%)	22 (0.04%)	33 (0.04%)	105 (0.07%)	59 (0.11%)
Angina	1399 (0.41%)	78 (0.15%)	195 (0.24%)	740 (0.47%)	386 (0.70%)
CABG/PTCA	1480 (0.43%)	67 (0.13%)	192 (0.24%)	785 (0.50%)	436 (0.79%)
Carotid artery disease	230 (0.07%)	7 (0.01%)	25 (0.03%)	116 (0.07%)	82 (0.15%)
Congestive heart failure	881 (0.26%)	42 (0.08%)	93 (0.12%)	400 (0.26%)	346 (0.63%)
Stroke	856 (0.25%)	36 (0.07%)	81 (0.10%)	407 (0.26%)	332 (0.61%)
PVD	202 (0.06%)	8 (0.02%)	23 (0.03%)	95 (0.06%)	76 (0.14%)
CHD[3]/Possible evolving Q-wave MI	1335 (0.39%)	82 (0.15%)	164 (0.20%)	632 (0.40%)	457 (0.83%)
Coronary disease[7]	3257 (0.95%)	184 (0.35%)	423 (0.53%)	1631 (1.04%)	1019 (1.86%)
Total cardiovascular disease	4245 (1.23%)	225 (0.42%)	524 (0.65%)	2120 (1.36%)	1376 (2.51%)
Fractures					
Hip fracture	367 (0.11%)	11 (0.02%)	27 (0.03%)	143 (0.09%)	186 (0.34%)
Vertebral fracture	430 (0.12%)	16 (0.03%)	47 (0.06%)	192 (0.12%)	175 (0.32%)
Other fracture[2]	4515 (1.31%)	566 (1.07%)	905 (1.13%)	2121 (1.36%)	923 (1.68%)
Total fracture	5110 (1.48%)	591 (1.12%)	969 (1.21%)	2365 (1.51%)	1185 (2.16%)
Deaths					
Cardiovascular deaths	531 (0.15%)	22 (0.04%)	40 (0.05%)	229 (0.15%)	240 (0.44%)
Cancer deaths	849 (0.25%)	54 (0.10%)	124 (0.15%)	413 (0.26%)	258 (0.47%)
Other known cause	318 (0.09%)	16 (0.03%)	38 (0.05%)	140 (0.09%)	124 (0.23%)
Unknown cause	88 (0.03%)	2 (<0.01%)	6 (0.01%)	46 (0.03%)	34 (0.06%)
Not yet adjudicated	87 (0.03%)	7 (0.01%)	8 (0.01%)	35 (0.02%)	37 (0.07%)
Total death	1873 (0.54%)	101 (0.19%)	216 (0.27%)	863 (0.55%)	693 (1.26%)

[1] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[2] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI.
[6] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[7] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 3.12 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Dietary Modification

Data as of: February 29, 2004

Outcome	Race/Ethnicity					
	American Indian/Alaska n Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	202	1105	5262	1845	39762	659
Mean follow-up (months)	82.6	81.2	83.0	79.9	85.3	80.3
Cancer						
Breast cancer	4 (0.29%)	43 (0.58%)	138 (0.38%)	48 (0.39%)	1567 (0.55%)	21 (0.48%)
Invasive breast cancer	4 (0.29%)	33 (0.44%)	103 (0.28%)	39 (0.32%)	1260 (0.45%)	17 (0.39%)
Non-invasive breast cancer	0 (0.00%)	10 (0.13%)	36 (0.10%)	9 (0.07%)	317 (0.11%)	4 (0.09%)
Ovarian cancer	1 (0.07%)	3 (0.04%)	10 (0.03%)	4 (0.03%)	128 (0.05%)	3 (0.07%)
Endometrial cancer[1]	0 (0.00%)	3 (0.04%)	16 (0.04%)	7 (0.06%)	219 (0.08%)	5 (0.11%)
Colorectal cancer	4 (0.29%)	6 (0.08%)	49 (0.13%)	16 (0.13%)	354 (0.13%)	7 (0.16%)
Other cancer[2]	5 (0.36%)	21 (0.28%)	123 (0.34%)	38 (0.31%)	1476 (0.52%)	21 (0.48%)
Total cancer	14 (1.01%)	72 (0.96%)	323 (0.89%)	107 (0.87%)	3608 (1.28%)	53 (1.20%)
Cardiovascular						
CHD[3]	3 (0.22%)	13 (0.17%)	127 (0.35%)	19 (0.15%)	952 (0.34%)	13 (0.29%)
CHD death[4]	0 (0.00%)	3 (0.04%)	47 (0.13%)	5 (0.04%)	218 (0.08%)	5 (0.11%)
Total MI[5]	3 (0.22%)	12 (0.16%)	94 (0.26%)	16 (0.13%)	806 (0.29%)	11 (0.25%)
Clinical MI	3 (0.22%)	11 (0.15%)	90 (0.25%)	16 (0.13%)	762 (0.27%)	10 (0.23%)
Evolving Q-wave MI[6]	0 (0.00%)	1 (0.01%)	4 (0.01%)	0 (0.00%)	46 (0.02%)	1 (0.02%)
Possible evolving Q-wave MI[6]	2 (0.14%)	7 (0.09%)	25 (0.07%)	6 (0.05%)	177 (0.06%)	2 (0.05%)
Angina	4 (0.29%)	15 (0.20%)	181 (0.50%)	40 (0.33%)	1138 (0.40%)	21 (0.48%)
CABG/PTCA	2 (0.14%)	11 (0.15%)	140 (0.38%)	27 (0.22%)	1286 (0.46%)	14 (0.32%)
Carotid artery disease	2 (0.14%)	1 (0.01%)	19 (0.05%)	2 (0.02%)	203 (0.07%)	3 (0.07%)
Congestive heart failure	1 (0.07%)	6 (0.08%)	144 (0.40%)	26 (0.21%)	692 (0.24%)	12 (0.27%)
Stroke	4 (0.29%)	18 (0.24%)	113 (0.31%)	19 (0.15%)	691 (0.24%)	11 (0.25%)
PVD	1 (0.07%)	2 (0.03%)	37 (0.10%)	2 (0.02%)	157 (0.06%)	3 (0.07%)
CHD[3]/Possible evolving Q-wave MI	5 (0.36%)	19 (0.25%)	152 (0.42%)	24 (0.20%)	1120 (0.40%)	15 (0.34%)
Coronary disease[7]	10 (0.72%)	36 (0.48%)	424 (1.17%)	78 (0.64%)	2666 (0.94%)	43 (0.97%)
Total cardiovascular disease	16 (1.15%)	55 (0.74%)	544 (1.50%)	99 (0.81%)	3475 (1.23%)	56 (1.27%)
Fractures						
Hip fracture	1 (0.07%)	1 (0.01%)	9 (0.02%)	6 (0.05%)	346 (0.12%)	4 (0.09%)
Vertebral fracture	1 (0.07%)	10 (0.13%)	6 (0.02%)	7 (0.06%)	400 (0.14%)	6 (0.14%)
Other fracture[2]	15 (1.08%)	72 (0.96%)	275 (0.76%)	108 (0.88%)	3988 (1.41%)	57 (1.29%)
Total fracture	16 (1.15%)	83 (1.11%)	287 (0.79%)	118 (0.96%)	4540 (1.61%)	66 (1.50%)
Deaths						
Cardiovascular deaths	2 (0.14%)	8 (0.11%)	79 (0.22%)	10 (0.08%)	425 (0.15%)	7 (0.16%)
Cancer deaths	6 (0.43%)	9 (0.12%)	79 (0.22%)	26 (0.21%)	717 (0.25%)	12 (0.27%)
Other known cause	6 (0.43%)	3 (0.04%)	43 (0.12%)	7 (0.06%)	256 (0.09%)	3 (0.07%)
Unknown cause	2 (0.14%)	1 (0.01%)	11 (0.03%)	2 (0.02%)	71 (0.03%)	1 (0.02%)
Not yet adjudicated	0 (0.00%)	2 (0.03%)	4 (0.01%)	1 (0.01%)	78 (0.03%)	2 (0.05%)
Total death	16 (1.15%)	23 (0.31%)	216 (0.59%)	46 (0.37%)	1547 (0.55%)	25 (0.57%)

[1] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[2] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI.
[6] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[7] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 3.13
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for DM Participants who did not report a prevalent condition at baseline

Data as of: February 29, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11039	22715	8120
Mean follow-up (months)	84.6	91.3	87.3	82.6	81.1
Hospitalizations					
Ever	22308 (6.48%)	2367 (4.47%)	4244 (5.29%)	10848 (6.94%)	4849 (8.84%)
Two or more	11434 (3.32%)	998 (1.88%)	1939 (2.42%)	5603 (3.58%)	2894 (5.27%)
Other					
DVT[1]	455 (0.14%)	27 (0.05%)	68 (0.09%)	215 (0.14%)	145 (0.28%)
Pulmonary embolism	299 (0.09%)	20 (0.04%)	43 (0.05%)	158 (0.10%)	78 (0.14%)
Diabetes (treated)	3188 (0.97%)	441 (0.86%)	708 (0.91%)	1480 (0.99%)	559 (1.08%)
Gallbladder disease[2]	3419 (1.19%)	514 (1.09%)	806 (1.18%)	1600 (1.25%)	499 (1.13%)
Hysterectomy	1386 (0.71%)	203 (0.68%)	318 (0.65%)	653 (0.75%)	212 (0.71%)
Glaucoma	4550 (1.37%)	471 (0.90%)	932 (1.19%)	2220 (1.48%)	927 (1.83%)
Osteoporosis	9102 (2.80%)	976 (1.88%)	1701 (2.19%)	4504 (3.08%)	1921 (3.92%)
Osteoarthritis[3]	8577 (4.04%)	1276 (3.25%)	2010 (3.68%)	3935 (4.33%)	1356 (4.95%)
Rheumatoid arthritis	2497 (0.75%)	339 (0.66%)	561 (0.72%)	1166 (0.78%)	431 (0.83%)
Intestinal polyps	6738 (2.10%)	849 (1.65%)	1482 (1.94%)	3379 (2.35%)	1028 (2.11%)
Lupus	428 (0.12%)	67 (0.13%)	102 (0.13%)	201 (0.13%)	58 (0.11%)
Kidney stones[3]	1094 (0.39%)	148 (0.35%)	242 (0.37%)	535 (0.41%)	169 (0.37%)
Cataracts[3]	13536 (5.26%)	920 (2.17%)	2375 (3.67%)	7466 (6.33%)	2775 (8.64%)
Pills for hypertension	11033 (4.59%)	1454 (3.42%)	2436 (4.02%)	5220 (4.98%)	1923 (5.91%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	202	1105	5262	1845	39762	659
Mean follow-up (months)	82.6	81.2	83.0	79.9	85.3	80.3
Hospitalizations						
Ever	84 (6.04%)	342 (4.58%)	2379 (6.54%)	698 (5.68%)	18526 (6.56%)	279 (6.32%)
Two or more	54 (3.89%)	138 (1.85%)	1273 (3.50%)	334 (2.72%)	9483 (3.36%)	152 (3.44%)
Other						
DVT[1]	0 (0.00%)	0 (0.00%)	42 (0.12%)	6 (0.05%)	400 (0.15%)	7 (0.16%)
Pulmonary embolism	2 (0.15%)	1 (0.01%)	30 (0.08%)	2 (0.02%)	260 (0.09%)	4 (0.09%)
Diabetes (treated)	15 (1.16%)	90 (1.28%)	595 (1.84%)	174 (1.51%)	2268 (0.83%)	46 (1.10%)
Gallbladder disease[2]	13 (1.31%)	51 (0.76%)	268 (0.83%)	140 (1.51%)	2902 (1.23%)	45 (1.19%)
Hysterectomy	4 (0.61%)	27 (0.57%)	88 (0.54%)	42 (0.64%)	1216 (0.74%)	9 (0.36%)
Glaucoma	24 (1.81%)	90 (1.25%)	650 (1.92%)	166 (1.40%)	3563 (1.31%)	57 (1.37%)
Osteoporosis	41 (3.10%)	237 (3.36%)	552 (1.58%)	346 (3.03%)	7803 (2.93%)	123 (3.01%)
Osteoarthritis[3]	41 (5.17%)	200 (3.71%)	870 (4.00%)	364 (4.37%)	6977 (4.03%)	125 (4.62%)
Rheumatoid arthritis	18 (1.44%)	46 (0.64%)	443 (1.30%)	200 (1.71%)	1745 (0.64%)	45 (1.08%)
Intestinal polyps	36 (2.80%)	148 (2.16%)	744 (2.19%)	215 (1.83%)	5500 (2.10%)	95 (2.35%)
Lupus	3 (0.22%)	5 (0.07%)	61 (0.17%)	16 (0.13%)	336 (0.12%)	7 (0.16%)
Kidney stones[3]	8 (0.73%)	18 (0.29%)	107 (0.36%)	50 (0.49%)	896 (0.39%)	15 (0.41%)
Cataracts[3]	54 (5.39%)	268 (4.72%)	1304 (4.75%)	458 (4.70%)	11272 (5.37%)	180 (5.43%)
Pills for hypertension	39 (4.37%)	236 (4.71%)	1176 (6.47%)	454 (4.97%)	8983 (4.40%)	145 (4.89%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

4. CaD Component

4.1 Recruitment

Table 4.1 – Calcium and Vitamin D Component Age – and Race/Ethnicity – Specific Recruitment presents the final sample size for number of women randomized in the Calcium and Vitamin D component of the WHI Clinical Trial. A total of 36,282 women have been randomized which is 80.6% of the overall goal of 45,000. The age distribution of the CaD trial participants is somewhat younger than anticipated in the design assumptions for the trial. Seventeen percent of women randomized are aged 70-79 years compared with the design assumption of 25%. Eighty-three percent of participants are white, 9% are African American and 4% are Hispanic.

4.2 Adherence

Table 4.2 – CaD Adherence Summary presents rates of follow-up, stopping intervention and pill collection, and adherence to pill taking by visit schedule for all CaD participants. The adherence summary for all CaD participants, defined as those women known to be consuming 80% or more of the prescribed dose, has remained steady since the last report (see *Figure 4.1 – CaD Adherence Summary*) at 55-62%. In the most recent time interval, September 2003 – February 2004, adherence rates edged slightly up at AV-6 to AV-8. About 23-38% of women on study medication take less than 80% of their CaD pills, but nonetheless remain partially adherent.

Table 4.3 – CaD Drop-out Rates by Follow-up Time summarizes interval and cumulative drop-out rates in comparison to the original design assumptions. The original power calculations for CaD assumed a 6% drop-out rate in year 1 and a 3% per year drop-out rate thereafter. An independent lost-to-follow-up rate of 3% per year was also incorporated, resulting in approximately 8.8% stopping intervention in year 1 and 5.9% in subsequent years. Drop-out rates in this report account for re-starting CaD, which results in lower rates than seen in early reports. At every annual visit, the observed drop-out rates are lower than design assumptions. Interval drop-out rates at AV-3 and beyond range from 3.1-5.3%, which compares favorably to the 5.9% design assumption. At AV-5, the cumulative drop-out rate was 20.1% (design assumption was 24.0%). From AV-6 through AV-8, observed cumulative rates are below the design assumption by about 4-7%.

Table 4.4 summarizes the frequency of reported reasons for stopping CaD. The majority of women stopping study supplements do so of their own accord. Only 7.8% have indicated that they were advised by their physician to discontinue these supplements. 1093 women (10.7%) reported other health problems or diseases, 2912 women (28.5%) reported symptoms, and 526 women (5.1%) reported that the study conflicts with other health issues. "Other pill issues" was the most frequently reported intervention-related reason (10.6%) followed by want to take her own calcium (4.1%). Miscellaneous reasons grouped together as "other reasons not listed above" were reported by 20.2% of women. Four common reasons for stopping CaD are shown first by age, and then by race/ethnicity, in *Table 4.5 – Reasons for Stopping CaD*. No strong associations by race/ethnicity are present, though "being advised by one's health care provider not to participate" and "study conflicts with other health issues" were slightly more common among white women. These reasons were reported with similar frequency by women in the various age groups.

We also monitor the number of women who have begun alternative anti-osteoporosis therapies within the CaD trial. As of February 29, 2004, 3009 (8.3%) of women were taking alendronate, 483 (1.3%) were taking risendronate, 281 (0.8%) were taking calcitonin, and 821 (2.3%) were taking raloxifene.

4.3 Bone Mineral Density

Table 4.6 – Bone Mineral Density Analysis: CaD Participants presents the mean bone mineral density levels at AV-1, AV-3, AV-6, and AV-9 and percent change in BMD during these intervals among women randomized at the three BMD measurement sites (Pittsburgh, Arizona, Birmingham). At the three skeletal sites examined (hip, spine, and whole body), BMD increased between AV-1 and AV-3 from 1.3-1.6%, with the greatest change occurring at the spine. The percent changes between AV-6 and AV-1 were approximately two times as large as those observed at AV-3 for the spine and whole body. At the hip, BMD change from AV-6 to AV-1 was 0.25%, less than the 1.27% increase observed at AV-3. For those few participants who have an AV-9 BMD measurement, spine and whole body BMD increased by 3-4%, whereas hip BMD declined by 0.10%.

Table 4.7 – Bone Mineral Density Analysis: CaD Participants presents the mean bone mineral density levels and percent change according to race/ethnicity. At AV-3 the rates of change relative to AV-1 were generally in the range of 1-2% gains for all skeletal sites. At AV-6, white and Hispanic/Latino women experienced BMD gains of approximately 1-6% at the various skeletal sites, whereas African American women had negative percent changes in BMD at the hip and whole body.

4.4 Vital Status

Table 4.8 – Lost-to-Follow-up and Vital Status presents data on the vital status and the participation status of participants in the CaD trial. A detailed description of CCC and clinic activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes Processing*. For operational purposes, we define CT participants to have an "unknown" participation status if there is no outcomes information from the participant for 18 months and no other contacts for 6 months. Currently, 2.3% of the participants are lost-to-follow-up or have stopped follow-up, and 3.3% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or death. Currently, the average follow-up for CaD participants is about 6.0 years, suggesting that approximately 16.7% could be expected to be dead or lost-to-follow-up. Our overall rates compare very favorably to design assumptions.

4.5 Outcomes

Table 4.9 – Verified Outcomes (Annualized Percentages) by Age and Race/Ethnicity for Calcium and Vitamin D contains counts of the number of verified major WHI outcomes for CaD participants. For the CaD component we are using centrally adjudicated outcomes for breast cancer, ovarian cancer, endometrial cancer, colorectal cancer, hip fractures, and death. Locally verified outcomes for events for which central adjudication has not yet been completed are included in the counts. In this table, only outcomes that took place after randomization in the CaD

trial are included. Approximately 3% of the self-reported outcomes have not yet been verified, so the numbers in this table should thus be seen as a lower bound to the actual number of outcomes that have taken place. Currently, with 274 cases of hip fracture locally verified, we have observed only about 45% of the number of hip fractures that were projected by the assumptions underlying the power calculations. The number of observed colorectal cancer cases (285 cases) is approximately 75%, the number of invasive breast cancer cases (916 cases) is approximately 115%, and the number of CHD cases (758 cases) is about 70% of what was expected.

Table 4.10 – Counts (Annualized Percentages) of Participants with Self-Reported Outcomes contains counts of the number of self-reports for some outcomes that are not locally verified in WHI. As most of the self-reported outcomes are somewhat over reported (see *Section 6.3 – Outcomes Data Quality*), the number in this table should be taken as an upper bound to the number of events that have occurred in CaD participants.

Table 4.1
Calcium and Vitamin D Component Age – and Race/Ethnicity – Specific Recruitment

Data as of: February 29, 2004

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**36,282**			
50-54	5,154	118%	14%	10%
55-59	8,268	94%	23%	20%
60-69	16,520	84%	46%	45%
70-79	6340	58%	17%	25%
Race/Ethnicity	**36,282**			
American Indian	149		<1%	
Asian	721		2%	
Black	3,315		9%	
Hispanic	1,502		4%	
White	30,155		83%	
Unknown	440		1%	

Table 4.2
CaD Adherence Summary
All CaD Participants

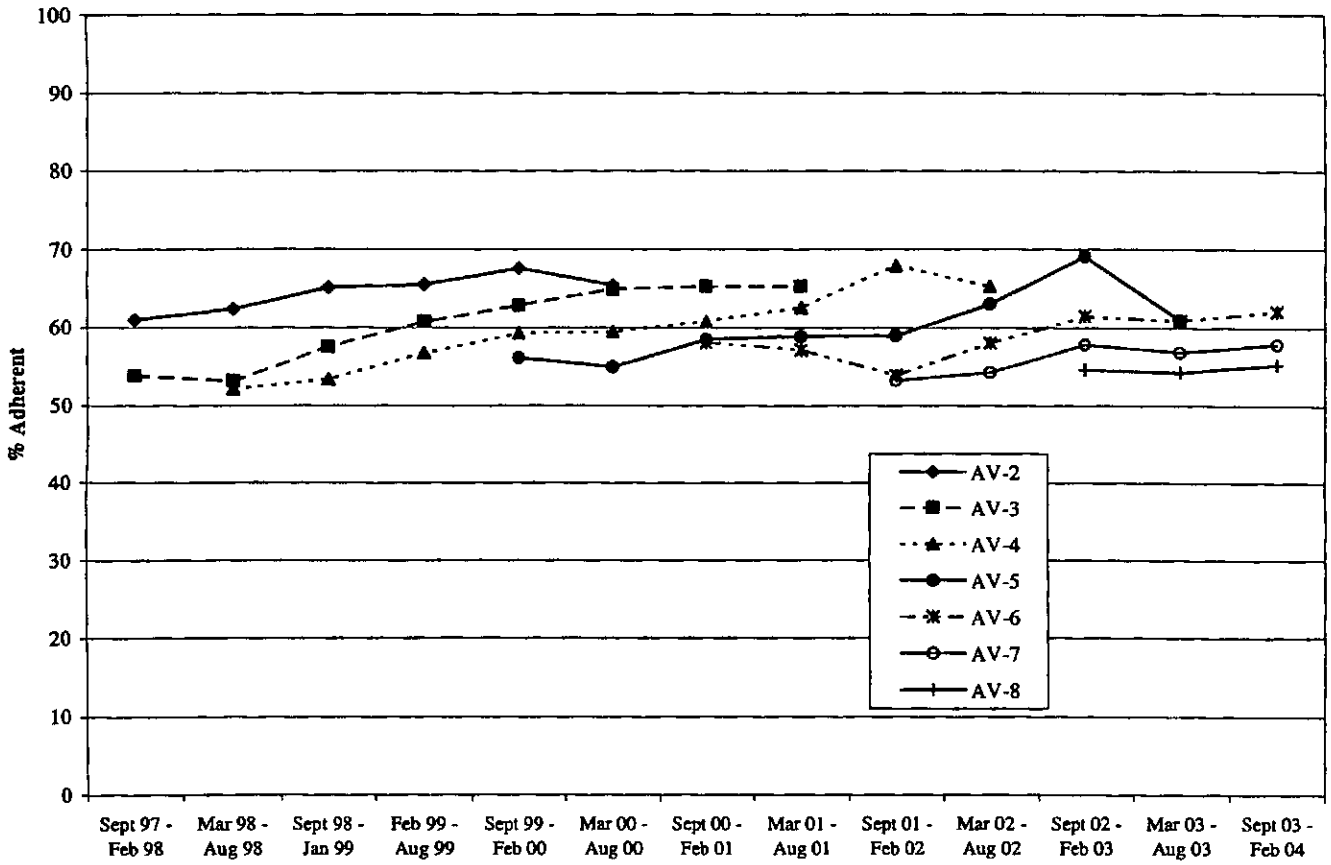
Data as of: February 29, 2004

	Due	Conducted[1]		Conducted in Window		Stopped CaD		Missed Pill Collection		Total with Collections		Medication Rate[2,3] <50%		Medication Rate[2,3] 50%-80%		Medication Rate[2,3] 80% +		Adherence Summary[4]
	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	%
Annual Visit - 2	33070	32260	98	25858	78	2375	7	124	0	32676	100	5755	18	7003	21	19918	61	60
Annual Visit - 3	36282	35242	97	26513	74	1924	5	363	1	33405	99	5367	16	5716	17	22322	66	62
Annual Visit - 4	36282	34767	96	24601	69	1576	4	399	1	31433	99	4274	13	4806	15	22353	70	62
Annual Visit - 5	36282	34515	95	23100	65	1407	4	380	1	29869	99	3700	12	4181	14	21988	73	62
Annual Visit - 6	33504	31680	95	19817	61	1150	4	408	2	26230	98	2906	11	3559	13	19765	74	60
Annual Visit - 7	22655	21096	93	12638	57	686	3	318	2	16865	98	1791	10	2245	13	12829	75	58
Annual Visit - 8	11381	10514	92	6006	55	336	3	183	2	8148	98	851	10	1076	13	6221	75	57
Annual Visit - 9	4342	3974	92	2237	54	165	4	87	3	2999	97	310	10	423	14	2266	73	55

[1] Based on *Form 33* collection.
[2] Medication rate calculated as the number of pills taken divided by the number of days since bottle(s) were dispensed.
[3] Percentage calculated based on denominator of total dispensation which is the sum of missed pill collection and total with collection.
[4] Adherence summary calculated as the number of women consuming ≥80% of pills divided by the number due for a visit.
Note: Deceased women are excluded from all medication adherence calculations, but are included in the number "Due."

Figure 4.1
CaD Adherence Summary
% Participants Due for a Visit Who Took at Least 80% of Study Pills[1]

Data as of: February 29, 2004



[1] Adherence calculations changed as of the September 2001 – February 2002 interval.

Table 4.3
CaD Drop-Out Rates by Follow-Up Time

Data as of: February 29, 2004

	Design		Observed			
	Int	Cum	Stopped[1]	Dead/ Lost[2]	Int[3]	Cum[4]
Drop-Outs[5]						
AV-2	8.8	8.8	7.2	0.2	7.2	7.1
AV-3	5.9	14.2	5.3	0.4	5.3	12.0
AV-4	5.9	19.2	4.4	0.6	4.4	16.2
AV-5	5.9	24.0	3.9	0.6	3.9	20.1
AV-6	5.9	28.5	3.5	0.7	3.5	23.6
AV-7	5.9	32.7	3.1	0.7	3.1	26.6
AV-8	5.9	36.7	3.1	0.8	3.1	29.5

[1] Estimated rate of stopping CaD in the interval.
[2] Death or lost to follow-up rate in the interval.
[3] The first event of stopping or death or lost to follow-up in the interval.
[4] Estimated cumulative rate of stopping or death or lost to follow-up. Cumulative rates calculated as Kaplan-Meier estimates.
[5] Drop-out rates derived from Form 7 by date.

Table 4.4
Reasons for Stopping CaD[1]

Data as of: February 29, 2004

Reasons[2]	(N = 10228)	
Personal/family		
Demands of work	206	2.0%
Family illness, emergency or other family demands[3]	379	3.7%
Financial problems	15	0.1%
Lack of cooperation/support from family/friends[4]	82	0.8%
Living in nursing home	70	0.7%
Issues of interest in study[5]	371	3.6%
Travel		
Too far to CC	249	2.4%
Moved out of area or refuses to be followed at another CC	96	0.9%
Other travel issues[6]	100	1.0%
Visits & Procedures		
Doesn't like visits, calls	91	0.9%
Doesn't like required forms or safety procedures[7]	87	0.9%
Problems with other procedures[8]	36	0.4%
Worried about health effects of medical tests/procedures	34	0.3%
Wants results of blood analyses	4	0.0%
Wants results of bone mineral density	2	0.0%
Problems with CC[9]	56	0.5%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted CaD.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Family illness, emergency or other family demands", "Death in the family or of a close friend", and "Caregiver responsibilities demanding time, effort, lifestyle changes".
[4] Combines "Lack of cooperation/support from family and/or friends" and "Family/friends request that she withdraw".
[5] Combines "Conflicting priorities other than work or family", "Feels discouraged regarding participation overall", "Loss of interest, boredom", "Feels it is not an important study", and "In another study in conflict with WHI intervention".
[6] Combines "Transportation problems (other than distance)", "Traffic", "Parking at CC", and "CC neighborhood/safety".
[7] Combines "Doesn't like filling out forms (other than those required for safety)", and "Doesn't like required safety forms and/or procedures".
[8] Combines "Doesn't like mammograms", "Cost of mammograms", "Doesn't like having blood drawn", "Doesn't like ECG", "Doesn't like gynecologic procedures" and "Doesn't like other procedures (other than those required for safety)".
[9] Combines "Problem with the CC", "Problem with CC staff person (other than DM Group Nutritionist)", and "Staff change/turnover".

Table 4.4 (continued)
Reasons for Stopping CaD[1]

Data as of: February 29, 2004

Reasons[2]	(N = 10228)	
Symptoms		
Bloating/gas	201	2.0%
Constipation	222	2.2%
Other gastrointestinal problems	269	2.6%
HRT Related Symptoms[3]	36	0.4%
Other[4]	2184	21.4%
Health Conditions		
Hypercalcemia		
Renal calculi	286	2.8%
Osteoporosis	262	2.6%
Other Diseases/Health Conditions[5]	96	0.9%
Communication difficulties[6]	1093	10.7%
	161	1.6%
Intervention		
Doesn't like randomized nature of intervention	363	3.5%
Expected some benefit from intervention	57	0.6%
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	20	0.2%
Takes too many pills	353	3.5%
Other pill issues[7]	1083	10.6%
HRT Issues[8]	167	1.6%
DM Issues[9]	16	0.2%
Wants to take her own calcium	415	4.1%
Feels diet is already sufficient in calcium/Vit D	52	0.5%
Taking more than the max allowable IU of Vit D	43	0.4%
Taking Calcitrol	23	0.2%
Other Health Issues		
Worried about cost if adverse effects occur	9	0.1%
Expected more health care	24	0.2%
Advised not to participate by health care provider[10]	801	7.8%
Study conflicts with other health issues[11]	526	5.1%
Other		
Other reasons not listed above	2068	20.2%
Refuses to give a reason	160	1.6%

[1] Does not include reasons reported by women who stopped and later restarted CaD.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Vaginal bleeding", "Breast tenderness", "Other breast changes", "Vaginal changes (e.g., dryness)", and "Hot flashes/night sweats".
[4] Combines "Experiencing health problems or symptoms not due to intervention", "Reports other health problems or symptoms from the WHI intervention", "Reports health problems or symptoms from the WHI intervention", "Hair/skin changes", "Headaches", "Weight loss/gain", "Low energy/too tired", "Possible allergic reaction", and "Other symptoms not listed above".
[5] Combines "Removed from intervention due to WHI symptom management", "Removed from intervention due to adverse health event", "Breast cancer", "Complex or atypical hyperplasia", "Endometrial cancer", "Deep vein thrombosis", "Pulmonary embolism", "Gallbladder disease", "Kidney failure/dialysis", "High triglycerides (> 1000 mg/dl)", "Malignant melanoma", "Meningioma", "Heart attack", "Stroke", "Arthritis", "Diabetes", "Depression", "Cholesterol (high or concern about levels)", and "Other health conditions not listed above".
[6] Combines "Communication problem", "Loss of vision and/or hearing", and "Cognitive/memory changes".
[7] Combines "Doesn't like taking pills", "Doesn't like taste of pills", and "Unable to swallow pills".
[8] Combines "Has made a personal decision to go on active HRT", "Has made a personal decision that she does not want to be on HRT", "Advised to go on active HRT by health care provider", "Advised to not be on active HRT by health care provider", "Has made a personal decision to go on SERM (e.g., Evista/raloxifene, tamoxifen)", "Advised to go on SERM (e.g., Evista/raloxifene, tamoxifen) by health care provider", and "Taking testosterone medications".
[9] Combines "Doesn't like DM requirements", "Problem with DM Group Nutritionist or group members", "Doesn't like DM eating pattern", "Doesn't like attending DM intervention classes", "Doesn't like self-monitoring", "Doesn't like budgeting fat grams", "Has concerns regarding long-term risks/benefits of low fat diet", "Unhappy that not losing weight", "Not in control of meal preparation", "Too difficult to meet or maintain dietary goals", "Doesn't like eating low fat diet", "Doesn't like eating 5 vegetables/fruits per day", "Doesn't like eating 6 grains per day", "Feels fat gram goal is unrealistic", and "Eating pattern conflicts with personal health beliefs".
[10] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason".
[11] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues".

Table 4.5
Reasons for Stopping CaD by Age at Screening and Race/Ethnicity[1]

Data as of: February 29, 2004

	All (N = 36,282)		Age at Screening: 50 – 54 (N = 5,154)		55 – 59 (N = 8,267)		60 – 69 (N = 16,519)		70 – 79 (N = 6,342)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping CaD	10228	28.2%	1561	30.3%	2224	26.9%	4356	26.4%	2087	32.9%
REASONS FOR STOPPING[3]										
Doesn't like randomized nature of intervention	363	3.5%	59	3.8%	82	3.7%	164	3.8%	58	2.8%
Other pill issues[4]	1083	10.6%	169	10.8%	251	11.3%	466	10.7%	197	9.4%
Advised not to participate by health care provider[5]	801	7.8%	88	5.6%	171	7.7%	365	8.4%	177	8.5%
Study conflicts with other health issues[6]	526	5.1%	67	4.3%	102	4.6%	230	5.3%	127	6.1%

	Race/Ethnicity: American Indian/ Alaskan Native (N = 149)		Asian/Pacific Islander (N = 721)		Black/African American (N = 3,315)		Hispanic/Latino (N = 1,502)		White (N = 30,155)		Unknown (N = 440)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping CaD	49	32.9%	204	28.3%	1073	32.4%	487	32.4%	8282	27.5%	133	30.2%
REASONS FOR STOPPING[3]												
Doesn't like randomized nature of intervention	0	0.0%	3	1.5%	31	2.9%	8	1.6%	317	3.8%	4	3.0%
Other pill issues[4]	5	10.2%	25	12.3%	99	9.2%	50	10.3%	894	10.8%	10	7.5%
Advised not to participate by health care provider[5]	3	6.1%	8	3.9%	63	5.9%	37	7.6%	682	8.2%	8	6.0%
Study conflicts with other health issues[6]	1	2.0%	7	3.4%	41	3.8%	19	3.9%	451	5.4%	7	5.3%

[1] Does not include reasons reported by women who stopped and later restarted CaD.
[2] Percentages are of CaD participants in the same age or race/ethnicity category.
[3] Multiple reasons may be reported for a woman.
[4] Combines "Doesn't like taking pills," "Doesn't like taste of pills," and "Unable to swallow pills."
[5] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason."
[6] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues."

Table 4.6
Bone Mineral Density[1] Analysis: CaD Participants

Data as of: February 29, 2004[2]

	N	Mean	S.D.
Whole Body Scan			
AV1	2440	1.02	0.11
AV3	2284	1.03	0.11
AV6	2023	1.05	0.12
AV9	528	1.06	0.14
AV3 % Change from AV1 BMD[3]	2211	1.46	3.39
AV6 % Change from AV1 BMD[3]	1955	2.25	5.33
AV9 % Change from AV1 BMD[3]	492	3.74	6.71
Spine Scan			
AV1	2354	0.99	0.16
AV3	2225	1.01	0.17
AV6	1957	1.02	0.17
AV9	503	1.00	0.17
AV3 % Change from AV1 BMD[3]	2156	1.58	4.21
AV6 % Change from AV1 BMD[3]	1891	2.74	6.00
AV9 % Change from AV1 BMD[3]	469	3.06	7.17
Hip Scan			
AV1	2431	0.86	0.14
AV3	2285	0.87	0.14
AV6	2040	0.87	0.14
AV9	523	0.85	0.14
AV3 % Change from AV1 BMD[3]	2211	1.27	3.55
AV6 % Change from AV1 BMD[3]	1963	0.25	5.06
AV9 % Change from AV1 BMD[3]	487	-0.10	5.98

[1] Measured in (g/cm^2).
[2] Because of technical problems, data from Birmingham are based on scans collected through October 2003 only.
[3] AVX % Change from AV1 BMD is defined as ((AVX-AV1)/AV1)x100.

Table 4.7
Bone Mineral Density[1] Analysis: CaD Participants by Race/Ethnicity

Data as of: February 29, 2004[2]

	Black/African American			Hispanic/Latino			White		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan									
AV1	279	1.08	0.11	123	1.04	0.12	2000	1.01	0.10
AV3	264	1.10	0.12	116	1.05	0.12	1868	1.03	0.11
AV6	225	1.08	0.12	115	1.10	0.15	1649	1.04	0.12
AV9	24	1.13	0.13	35	1.14	0.20	463	1.05	0.13
AV3 % Change from AV1 BMD[3]	260	1.23	3.01	104	2.20	4.36	1813	1.45	3.38
AV6 % Change from AV1 BMD[3]	220	-0.33	3.77	97	5.94	7.25	1607	2.40	5.21
AV9 % Change from AV1 BMD[3]	22	2.56	6.50	26	6.12	6.71	439	3.64	6.73
Spine Scan									
AV1	274	1.07	0.18	118	0.98	0.16	1924	0.98	0.16
AV3	260	1.08	0.19	113	0.97	0.15	1816	1.00	0.17
AV6	210	1.08	0.18	113	0.98	0.16	1600	1.01	0.17
AV9	24	1.12	0.15	34	0.96	0.16	439	1.00	0.17
AV3 % Change from AV1 BMD[3]	256	1.15	4.40	101	0.38	3.99	1765	1.75	4.18
AV6 % Change from AV1 BMD[3]	205	1.01	6.17	95	1.29	5.76	1560	3.06	5.95
AV9 % Change from AV1 BMD[3]	22	1.14	7.25	25	2.76	6.90	417	3.16	7.21
Hip Scan									
AV1	279	0.98	0.14	123	0.87	0.14	1991	0.85	0.13
AV3	264	0.98	0.15	116	0.88	0.13	1869	0.86	0.13
AV6	229	0.96	0.14	117	0.89	0.14	1660	0.86	0.13
AV9	24	0.97	0.14	35	0.89	0.16	458	0.84	0.13
AV3 % Change from AV1 BMD[3]	260	0.85	3.16	103	1.74	4.74	1814	1.30	3.51
AV6 % Change from AV1 BMD[3]	223	-1.96	4.35	98	2.78	5.30	1611	0.43	5.00
AV9 % Change from AV1 BMD[3]	22	-1.27	4.84	26	2.52	4.37	435	-0.25	6.06

[1] Measured in (g/cm^2).
[2] Because of technical problems, data from Birmingham are based on scans collected through October 2003 only.
[3] AVX % Change from AV1 BMD is defined as ((AVX-AV1)/AV1)x100.

Table 4.8
Lost-to-Follow-up and Vital Status: CaD Participants

Data as of: February 29, 2004

	CaD Participants (N = 36,282) N	%
Vital Status/Participation		
Deceased	1208	3.3
Alive: Current Participation[1]	33840	93.3
Alive: Recent Participation[2]	381	1.1
Alive: Past/Unknown Participation[3]	8	<0.1
Stopped Follow-Up[4]	513	1.4
Lost to Follow-Up[5]	332	0.9

[1] Participants who have filled in a Form 33 within the last 9 months.
[2] Participants who last filled in a Form 33 between 9 and 18 months ago.
[3] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 4.9
Verified Outcomes (Annualized Percentages) by Age for Calcium and Vitamin D

Data as of: February 29, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number of participants	36282	5154	8268	16520	6340
Mean follow-up (months)	72.0	77.9	74.4	70.2	68.6
Fractures					
Hip fracture	274 (0.13%)	5 (0.01%)	25 (0.05%)	99 (0.10%)	145 (0.40%)
Vertebral fracture	283 (0.13%)	7 (0.02%)	31 (0.06%)	120 (0.12%)	125 (0.35%)
Other fracture[1]	3057 (1.40%)	381 (1.14%)	614 (1.20%)	1398 (1.45%)	664 (1.83%)
Total fracture	3473 (1.60%)	392 (1.17%)	662 (1.29%)	1553 (1.61%)	866 (2.39%)
Cancer					
Colorectal cancer	285 (0.13%)	20 (0.06%)	39 (0.08%)	142 (0.15%)	84 (0.23%)
Breast cancer	1155 (0.53%)	133 (0.40%)	271 (0.53%)	551 (0.57%)	200 (0.55%)
Invasive breast cancer	916 (0.42%)	95 (0.28%)	220 (0.43%)	441 (0.46%)	160 (0.44%)
Non-invasive breast cancer	245 (0.11%)	38 (0.11%)	52 (0.10%)	112 (0.12%)	43 (0.12%)
Ovarian cancer	94 (0.04%)	9 (0.03%)	26 (0.05%)	38 (0.04%)	21 (0.06%)
Endometrial cancer[2]	150 (0.12%)	17 (0.09%)	34 (0.11%)	70 (0.12%)	29 (0.14%)
Other cancer[1]	1138 (0.52%)	101 (0.30%)	194 (0.38%)	551 (0.57%)	292 (0.81%)
Total cancer	2734 (1.26%)	275 (0.82%)	552 (1.08%)	1304 (1.35%)	603 (1.66%)
Cardiovascular					
CHD[3]	758 (0.35%)	45 (0.13%)	88 (0.17%)	355 (0.37%)	270 (0.75%)
CHD death[4]	189 (0.09%)	11 (0.03%)	18 (0.04%)	70 (0.07%)	90 (0.25%)
Total MI[5]	629 (0.29%)	36 (0.11%)	73 (0.14%)	312 (0.32%)	208 (0.57%)
Clinical MI	581 (0.27%)	32 (0.10%)	68 (0.13%)	290 (0.30%)	191 (0.53%)
Evolving Q-wave MI[6]	50 (0.02%)	4 (0.01%)	5 (0.01%)	24 (0.02%)	17 (0.05%)
Possible evolving Q-wave MI[6]	179 (0.08%)	20 (0.06%)	28 (0.05%)	75 (0.08%)	56 (0.15%)
Angina	925 (0.43%)	45 (0.13%)	132 (0.26%)	475 (0.49%)	273 (0.75%)
CABG/PTCA	1018 (0.47%)	52 (0.16%)	130 (0.25%)	523 (0.54%)	313 (0.86%)
Carotid artery disease	169 (0.08%)	7 (0.02%)	15 (0.03%)	93 (0.10%)	54 (0.15%)
Congestive heart failure	592 (0.27%)	24 (0.07%)	65 (0.13%)	279 (0.29%)	224 (0.62%)
Stroke	584 (0.27%)	26 (0.08%)	57 (0.11%)	266 (0.28%)	235 (0.65%)
PVD	152 (0.07%)	5 (0.01%)	18 (0.04%)	70 (0.07%)	59 (0.16%)
CHD[3]/Possible evolving Q-wave MI	928 (0.43%)	65 (0.19%)	115 (0.22%)	424 (0.44%)	324 (0.89%)
Coronary disease[7]	2225 (1.02%)	124 (0.37%)	297 (0.58%)	1076 (1.11%)	728 (2.01%)
Total cardiovascular disease	2922 (1.34%)	155 (0.46%)	370 (0.72%)	1422 (1.47%)	975 (2.69%)
Deaths					
Cardiovascular deaths	340 (0.16%)	16 (0.05%)	28 (0.05%)	138 (0.14%)	158 (0.44%)
Cancer deaths	552 (0.25%)	41 (0.12%)	78 (0.15%)	264 (0.27%)	169 (0.47%)
Other known cause	200 (0.09%)	8 (0.02%)	27 (0.05%)	95 (0.10%)	70 (0.19%)
Unknown cause	56 (0.03%)	2 (0.01%)	11 (0.02%)	27 (0.03%)	16 (0.04%)
Not yet adjudicated	60 (0.03%)	5 (0.01%)	4 (0.01%)	25 (0.03%)	26 (0.07%)
Total death	1208 (0.56%)	72 (0.22%)	148 (0.29%)	549 (0.57%)	439 (1.21%)

[1] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[2] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI.
[6] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[7] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 4.9 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Calcium and Vitamin D

Data as of: February 29, 2004

Outcome	Race/Ethnicity					
	American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number of participants	149	721	3315	1502	30155	440
Mean follow-up (months)	71.9	68.1	70.7	70.0	72.4	68.3
Fractures						
Hip fracture	1 (0.11%)	4 (0.10%)	5 (0.03%)	2 (0.02%)	262 (0.14%)	0 (0.00%
Vertebral fracture	1 (0.11%)	4 (0.10%)	3 (0.02%)	6 (0.07%)	262 (0.14%)	7 (0.28%
Other fracture[1]	14 (1.57%)	38 (0.93%)	153 (0.78%)	77 (0.88%)	2743 (1.51%)	32 (1.28%
Total fracture	16 (1.79%)	45 (1.10%)	160 (0.82%)	85 (0.97%)	3129 (1.72%)	38 (1.52%
Cancer						
Colorectal cancer	3 (0.34%)	4 (0.10%)	24 (0.12%)	9 (0.10%)	242 (0.13%)	3 (0.12%
Breast cancer	3 (0.34%)	23 (0.56%)	77 (0.39%)	35 (0.40%)	1007 (0.55%)	10 (0.40%
Invasive breast cancer	3 (0.34%)	15 (0.37%)	58 (0.30%)	29 (0.33%)	801 (0.44%)	10 (0.40%
Non-invasive breast cancer	0 (0.00%)	8 (0.20%)	20 (0.10%)	6 (0.07%)	211 (0.12%)	0 (0.00%
Ovarian cancer	0 (0.00%)	2 (0.05%)	7 (0.04%)	2 (0.02%)	82 (0.05%)	1 (0.04%
Endometrial cancer[2]	1 (0.27%)	2 (0.08%)	4 (0.05%)	3 (0.06%)	138 (0.13%)	2 (0.14%
Other cancer[1]	3 (0.34%)	17 (0.42%)	71 (0.36%)	25 (0.29%)	1011 (0.56%)	11 (0.44%
Total cancer	10 (1.12%)	46 (1.12%)	179 (0.92%)	69 (0.79%)	2403 (1.32%)	27 (1.08%
Cardiovascular						
CHD[3]	5 (0.56%)	4 (0.10%)	77 (0.39%)	17 (0.19%)	644 (0.35%)	11 (0.44%
CHD death[4]	1 (0.11%)	2 (0.05%)	32 (0.16%)	3 (0.03%)	148 (0.08%)	3 (0.12%
Total MI[5]	5 (0.56%)	3 (0.07%)	51 (0.26%)	15 (0.17%)	545 (0.30%)	10 (0.40%
Clinical MI	5 (0.56%)	3 (0.07%)	48 (0.25%)	15 (0.17%)	501 (0.28%)	9 (0.36%
Evolving Q-wave MI[6]	0 (0.00%)	0 (0.00%)	3 (0.02%)	0 (0.00%)	46 (0.03%)	1 (0.04%
Possible evolving Q-wave MI[6]	0 (0.00%)	5 (0.12%)	21 (0.11%)	7 (0.08%)	146 (0.08%)	0 (0.00%
Angina	2 (0.22%)	10 (0.24%)	94 (0.48%)	35 (0.40%)	771 (0.42%)	13 (0.52%
CABG/PTCA	4 (0.45%)	7 (0.17%)	87 (0.45%)	30 (0.34%)	876 (0.48%)	14 (0.56%
Carotid artery disease	1 (0.11%)	1 (0.02%)	8 (0.04%)	2 (0.02%)	155 (0.09%)	2 (0.08%
Congestive heart failure	2 (0.22%)	4 (0.10%)	80 (0.41%)	22 (0.25%)	478 (0.26%)	6 (0.24%
Stroke	5 (0.56%)	16 (0.39%)	64 (0.33%)	14 (0.16%)	476 (0.26%)	9 (0.36%
PVD	1 (0.11%)	2 (0.05%)	19 (0.10%)	1 (0.01%)	128 (0.07%)	1 (0.04%
CHD[3]/Possible evolving Q-wave MI	5 (0.56%)	9 (0.22%)	97 (0.50%)	23 (0.26%)	783 (0.43%)	11 (0.44%
Coronary disease[7]	7 (0.78%)	21 (0.51%)	245 (1.25%)	67 (0.76%)	1859 (1.02%)	26 (1.04%
Total cardiovascular disease	11 (1.23%)	36 (0.88%)	314 (1.61%)	84 (0.96%)	2441 (1.34%)	36 (1.44%
Deaths						
Cardiovascular deaths	1 (0.11%)	7 (0.17%)	51 (0.26%)	6 (0.07%)	272 (0.15%)	3 (0.12%
Cancer deaths	1 (0.11%)	11 (0.27%)	44 (0.23%)	14 (0.16%)	476 (0.26%)	6 (0.24%
Other known cause	5 (0.56%)	2 (0.05%)	23 (0.12%)	2 (0.02%)	166 (0.09%)	2 (0.08%
Unknown cause	1 (0.11%)	1 (0.02%)	9 (0.05%)	1 (0.01%)	42 (0.02%)	2 (0.08%
Not yet adjudicated	0 (0.00%)	1 (0.02%)	1 (0.01%)	3 (0.03%)	53 (0.03%)	2 (0.08%
Total death	8 (0.90%)	22 (0.54%)	128 (0.66%)	26 (0.30%)	1009 (0.55%)	15 (0.60%

[1] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[2] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI.
[6] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[7] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 4.10
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CaD Participants who did not report a prevalent condition at baseline

Data as of: February 29, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	36282	5154	8268	16520	6340
Mean follow-up (months)	72.0	77.9	74.4	70.2	68.6
Hospitalizations					
Ever	14958 (6.87%)	1542 (4.61%)	2843 (5.54%)	7141 (7.39%)	3432 (9.47%)
Two or more	7198 (3.31%)	619 (1.85%)	1236 (2.41%)	3447 (3.57%)	1896 (5.23%)
Other					
DVT[1]	333 (0.16%)	18 (0.05%)	57 (0.11%)	152 (0.16%)	106 (0.30%)
Pulmonary embolism	204 (0.09%)	16 (0.05%)	34 (0.07%)	109 (0.11%)	45 (0.13%)
Diabetes (treated)	2300 (1.10%)	342 (1.05%)	513 (1.04%)	1051 (1.14%)	394 (1.15%)
Gallbladder disease[2]	2145 (1.17%)	326 (1.10%)	531 (1.20%)	978 (1.22%)	310 (1.05%)
Hysterectomy	838 (0.66%)	118 (0.61%)	200 (0.63%)	388 (0.69%)	132 (0.65%)
Glaucoma	3108 (1.48%)	329 (1.00%)	625 (1.25%)	1499 (1.61%)	655 (1.94%)
Osteoporosis	6191 (2.99%)	625 (1.90%)	1139 (2.29%)	3011 (3.28%)	1416 (4.30%)
Osteoarthritis[3]	5804 (4.27%)	867 (3.48%)	1356 (3.86%)	2631 (4.59%)	950 (5.13%)
Rheumatoid arthritis	1586 (0.76%)	228 (0.70%)	375 (0.76%)	708 (0.76%)	275 (0.80%)
Intestinal polyps	4428 (2.18%)	559 (1.73%)	960 (1.96%)	2173 (2.43%)	736 (2.28%)
Lupus	293 (0.14%)	50 (0.15%)	68 (0.13%)	122 (0.13%)	53 (0.15%)
Kidney stones[3]	654 (0.35%)	92 (0.34%)	150 (0.35%)	297 (0.36%)	115 (0.37%)
Cataracts[3]	9673 (5.94%)	670 (2.50%)	1732 (4.17%)	5202 (7.11%)	2069 (9.68%)
Pills for hypertension	8178 (5.26%)	1084 (3.97%)	1803 (4.56%)	3782 (5.70%)	1509 (6.78%)

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	149	721	3315	1502	30155	440
Mean follow-up (months)	71.9	68.1	70.7	70.0	72.4	68.3
Hospitalizations						
Ever	65 (7.28%)	207 (5.06%)	1396 (7.15%)	514 (5.87%)	12597 (6.93%)	179 (7.15%)
Two or more	42 (4.70%)	82 (2.00%)	700 (3.58%)	222 (2.53%)	6058 (3.33%)	94 (3.75%)
Other						
DVT[1]	2 (0.23%)	0 (0.00%)	30 (0.16%)	5 (0.06%)	293 (0.17%)	3 (0.12%)
Pulmonary embolism	3 (0.34%)	0 (0.00%)	18 (0.09%)	2 (0.02%)	178 (0.10%)	3 (0.12%)
Diabetes (treated)	10 (1.21%)	66 (1.72%)	357 (2.05%)	157 (1.91%)	1677 (0.95%)	33 (1.41%)
Gallbladder disease[2]	10 (1.47%)	31 (0.83%)	143 (0.81%)	99 (1.47%)	1836 (1.20%)	26 (1.24%)
Hysterectomy	2 (0.53%)	14 (0.53%)	40 (0.48%)	29 (0.60%)	748 (0.68%)	5 (0.35%)
Glaucoma	18 (2.12%)	51 (1.30%)	393 (2.15%)	147 (1.73%)	2473 (1.41%)	26 (1.10%)
Osteoporosis	25 (2.94%)	135 (3.42%)	325 (1.73%)	259 (3.15%)	5377 (3.11%)	70 (2.99%)
Osteoarthritis[3]	33 (5.86%)	118 (3.96%)	512 (4.32%)	284 (4.74%)	4773 (4.23%)	84 (5.12%)
Rheumatoid arthritis	13 (1.64%)	24 (0.61%)	260 (1.44%)	133 (1.59%)	1136 (0.65%)	20 (0.85%)
Intestinal polyps	28 (3.41%)	74 (1.96%)	436 (2.39%)	146 (1.74%)	3694 (2.18%)	50 (2.17%)
Lupus	4 (0.46%)	1 (0.02%)	33 (0.17%)	11 (0.13%)	242 (0.13%)	2 (0.08%)
Kidney stones[3]	6 (0.81%)	13 (0.37%)	52 (0.32%)	34 (0.46%)	542 (0.35%)	7 (0.33%)
Cataracts[3]	44 (6.44%)	157 (5.07%)	787 (5.34%)	385 (5.54%)	8187 (6.04%)	113 (5.88%)
Pills for hypertension	32 (5.70%)	151 (5.37%)	777 (7.66%)	382 (5.66%)	6744 (5.05%)	92 (5.78%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

5. Observational Study

5.1 Recruitment

Recruitment into the OS component, completed in December of 1998, reached 93,717, approximately 94% of the expected sample size. After removing duplicate enrollments and a few enrollments with insufficient data, the final analytic cohort was established with 93,676 participants. *Table 5.1 – Observation Study Age and Race/Ethnicity Specific Recruitment* documents the age distribution and the racial/ethnic composition of this cohort.

5.2 Overview of Follow-up

OS follow-up is conducted by annual mailed self-administered questionnaires except for year 3, when participants attend a clinic follow-up visit. Participants at the 3 bone density sites also attend clinic visits at years 6 and 9 for a bone density scan. For all other years, the CCC mails the *Medical History Update* and the *OS Exposure Update* questionnaires approximately 2 months prior to the anniversary of the participants' enrollment. Participants mail their completed questionnaires to their local CC for data entry and outcomes processing. Non-respondents receive up to two additional mailings from the CCC. For odd numbered follow-up years, CCs attempt to complete follow-up of non-responders by local contacts, usually telephone reminders or interviews.

The year 3 clinic visit was incorporated to assess change in physical measures, blood analytes, diet, and use of medications and supplements. These visits began in the first CCs in Fall 1997. Year 6 visits at bone density sites started in 2000 and year 9 started in 2003.

5.3 Completeness of Annual Mail Follow-up

Table 5.2 – Response Rates to OS Follow-up Procedures shows completeness of OS mail follow-up by follow-up year, type of contact, and clinic group. These rates include participants for whom the full sequence of mailings is complete and there has been at least two months for CC follow-up of non-responders, as of 2/29/04.

The overall response of 95.7% for year 1 data collection, which includes mailings plus CC follow-up of non-responders, slightly exceeds the 95% goal for completion of *Form 48 – OS Exposure Update*, but falls short of the optimal goal (98%) for completion of *Form 33 – Medical History Update*. For years 2, 4, 5, 6, 7, and 8 the rates of 94.0% (Y2), 93.6% (Y4), 94.2% (Y5), 93.6% (Y6), 94.6% (Y7), and 94.1% (Y8) exceed or meet the 94% (Y2), 92% (Y4), 91% (Y5), 90% (Y6), 90% (Y7), and 90% (Y8) goals for the *Exposure Update*. These rates fall slightly short of the optimal goals (98% at Y1 with a 0.5% annual decline to 94.5% by Y8) for the *Medical History Update*.

5.4 Completeness of Clinic Visits (Years 3, 6, and 9)

Table 5.3 – OS Annual Visit 3/6 Task Completeness shows completeness of activities conducted at the year 3 clinic visit for all participants and at the year 6 visit for bone density participants. Of those participants due for the year 3 visit through 2/29/04, 96.1% overall completed *Form 33 – Medical History Updates* and 82.7% provided *Form 100 – Blood Samples*. Of those participants at the 3 bone densitometry substudy clinics due for the year 6 visit, 87.4% completed *Form 33 –*

Medical History Updates and 77.2% completed *Form 87 – Bone Densitometry.* Rates for the year 9 visit are not yet available.

5.5 Bone Mineral Density

Bone scans are given to all enrolled WHI participants in three Clinical Centers: Birmingham, Pittsburgh, and Tucson. The choice of three centers was based on reducing the variability associated with multiple sites and operators while achieving adequate sample size. The selection of these three clinical centers was based both on their previous experience in bone densitometry and the expected enrollment of minorities which will allow us to address hypotheses regarding racial/ethnic differences. Bone scans are given at baseline and years 1, 3, 6, and 9 in these centers.

Table 5.4 – Bone Mineral Density Analysis (OS participants) and *Table 5.5* (by race and ethnicity) show the OS component-specific BMD means and standard deviations for baseline, AV-3, AV-6, and AV-9, along with % change from baseline for the three types of scans available: whole body, spine, and hip. Baseline and % change at AV-3 is given using only those women who have an AV-3 bone scan; this is also the case for AV-6 and AV-9 data. The current data suggest overall a small increase in bone density, as measured by the whole body scan, over three, six, and nine years in this group of women. In general, we would have expected a small decrease in BMD over time. As with the corresponding DM results, this increase could be related to some selection of health conscious women who may be taking hormone replacement therapy or calcium supplements of their own, or could be due to measurement issues.

5.6 Vital Status

Table 5.6 – Lost-to-Follow-up and Vital Status: OS Participants presents data on the vital status and the participation status of participants in the OS. A detailed description of CC and CCC activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes Processing.* For operational purposes, we define OS participants to be lost-to-follow-up if there is no outcomes information from the participant for 24 months. Currently, 1.6% of the participants are lost-to-follow-up, and an additional 1.9% of the participants have stopped follow-up. 4.7% of the OS participants are deceased.

5.7 Outcomes

Table 5.7 – Verified Outcomes (Annualized Percentages) for OS Participants contains counts of the number of verified major WHI outcomes for OS participants by age and race/ethnicity. As approximately 4% of the self-reported outcomes have not yet been verified, the numbers in this table can be seen as a lower bound to the actual number of outcomes that took place. For the OS component we are using centrally adjudicated outcomes for breast cancer, ovarian cancer, endometrial cancer, colorectal cancer, and hip fractures. Locally verified outcomes for events for which central adjudication has not yet been completed are included in the counts. Compared to the incidence rates used in the CT design, we have about 130% of the expected number of breast cancers, 65% of the expected number of colorectal cancers, about 55% of the expected number of CHD events, and about 40% of the expected number hip fractures.

Table 5.8 – Counts (Annualized Percentages) of Participants with Self Reported Outcomes by Age and Race/Ethnicity for OS Participants contains counts of the number of self-reports for some outcomes that are not verified in WHI. As most of the locally verified outcomes are somewhat

over-reported (see *Section 6.3 – Outcomes Data Quality*), the number in this table should be taken as an upper bound to the number of events that have occurred among OS participants.

Tables 5.9 – First Reported Verified Outcomes and *5.10 – Counts of Participants with Self-Reported Outcomes*, contain counts of outcomes relative to AV-3. These tables count the *first* event of a particular type, thus a participant who reports, say, a myocardial infarction at AV-1 and another one at AV-4 gets only counted in the "Before AV-3" category. These tables may be useful for investigators who want to propose ancillary studies or papers.

Table 5.1
Observational Study Age and Race/Ethnicity Specific Recruitment

Data as of: February 29, 2004

	Total Enrolled	Distribution
Age	**93,676**	
50-54	12,383	13%
55-59	17,323	18%
60-69	41,199	44%
70-79	22,771	24%
Race/Ethnicity	**93,676**	
American Indian	421	<1%
Asian	2,671	3%
Black	7,635	8%
Hispanic	3,609	4%
White	78,016	83%
Unknown	1,324	1%

Table 5.2
Response Rates to OS Follow-up Procedures

Data as of: February 29, 2004

	# Due[1]	Mailings Initiated[2] N	%	Response to Mailings N	%[3]	Response to CC follow-up N	%[4]	Total Responses N	%[5]
Year 1	93,479	93,294	99.8%	86,610	92.8%	2,813	42.1%	89,423	95.7%
VCC	41,642	41,608	99.9%	38,400	92.3%	1,678	52.3%	40,078	96.2%
NCC	51,837	51,686	99.7%	48,210	93.3%	1,135	32.7%	49,345	95.2%
Year 2	93,039	91,400	98.2%	86,194	94.3%	N/A		87,463	94.0%
VCC	41,458	40,711	98.2%	38,417	94.4%	N/A		39,026	94.1%
NCC	51,581	50,689	98.3%	47,777	94.3%	N/A		48,437	93.9%
Year 4	91,814	90,075	98.1%	84,001	93.3%	N/A		85,897	93.6%
VCC	40,919	40,133	98.1%	37,254	92.8%	N/A		38,034	92.9%
NCC	50,895	49,942	98.1%	46,747	93.6%	N/A		47,863	94.0%
Year 5	74,009	72,444	97.9%	68,045	93.9%	1,699	38.6%	69,744	94.2%
VCC	33,436	32,864	98.3%	30,654	93.3%	753	34.1%	31,407	93.9%
NCC	40,573	39,580	97.6%	37,391	94.5%	946	43.2%	38,337	94.5%
Year 6[6]	48,121	46,892	97.4%	43,964	93.8%	N/A		45,034	93.6%
VCC	20,045	19,594	97.8%	18,213	93.0%	N/A		18,610	92.8%
NCC	28,076	27,298	97.2%	25,751	94.3%	N/A		26,424	94.1%
Year 7	26,149	25,359	97.0%	24,139	95.2%	603	49.4%	24,742	94.6%
VCC	13,458	13,089	97.3%	12,349	94.3%	304	41.1%	12,653	94.0%
NCC	12,691	12,270	96.7%	11,790	96.1%	299	62.3%	12,089	95.3%
Year 8	2,522	2,457	97.4%	2,304	93.8%	N/A		2,372	94.1%
VCC	2,491	2,427	97.4%	2,276	93.8%	N/A		2,343	94.1%
NCC	31	30	96.8%	28	93.3%	N/A		29	93.5%

[1] Excludes women who are deceased.
[2] Mailings are not sent to women who have requested no follow-up, who are deceased, who have a non-deliverable address at the time of mailing, or who have a *Form 33* completed within the previous 3 months.
[3] Percent response of those initiated.
[4] Percent response from OS participants not responding to mailings. CC follow-up not required in even numbered follow-up years.
[5] Percent response of those due.
[6] Does not include bone density sites.

Table 5.3
OS Annual Visit 3/6 Task Completeness

Data as of: February 29, 2004

	Task	# Due[1]	# Done[2]	% Done
Year 3	Form 33 - Medical History Update	92,478	88,854	96.1%
	Form 38 - Daily Life	92,478	82,337	89.0%
	Form 44 - Current Medications	92,478	79,266	85.7%
	Form 45 - Current Supplements	92,478	79,165	85.6%
	Form 60 - Food Frequency Quest	92,478	82,499	89.2%
	Form 80 - Physical Measures	92,478	77,385	83.7%
	Form 100 - Blood Collection	92,478	76,488	82.7%
	Form 143 - Follow-up	92,478	81,974	88.6%
Year 6[3]	Form 33 - Medical History Update	5,283	4,618	87.4%
	Form 80 - Physical Measures	5,283	4,087	77.4%
	Form 87 - Bone Densitometry	5,283	4,076	77.2%
	Form 146 - Follow-up	5,283	4,379	82.9%

[1] Includes all Year 3/6 contacts due through 10/31/02. Excludes women who are deceased.
[2] Tasks completed within the -6/+15 month window for Year 3 and -2/+10 month window for Year 6.
[3] Includes bone density sites only.

Table 5.4
Bone Mineral Density[1] Analysis: OS Participants

Data as of: February 29, 2004[2]

	N	Mean	S.D.
Whole Body Scan			
Baseline	6415	1.01	0.11
Baseline (for ppts. with an AV3 scan)	5103	1.01	0.11
Baseline (for ppts. with an AV6 scan)	4224	1.01	0.11
Baseline (for ppts. with an AV9 scan)	665	1.01	0.10
AV3	5158	1.02	0.11
AV6	4269	1.03	0.12
AV9	672	1.03	0.12
AV3 % Change from baseline BMD[3]	5096	0.95	3.70
AV6 % Change from baseline BMD[3]	4210	1.96	5.59
AV9 % Change from baseline BMD[3]	665	1.46	6.31
Spine Scan			
Baseline	6247	0.98	0.17
Baseline (for ppts. with an AV3 scan)	5006	0.97	0.17
Baseline (for ppts. with an AV6 scan)	4067	0.97	0.17
Baseline (for ppts. with an AV9 scan)	650	0.96	0.16
AV3	5045	0.99	0.18
AV6	4102	1.01	0.18
AV9	653	1.01	0.18
AV3 % Change from baseline BMD[3]	4998	1.68	5.15
AV6 % Change from baseline BMD[3]	4052	3.33	6.97
AV9 % Change from baseline BMD[3]	650	4.83	8.16
Hip Scan			
Baseline	6419	0.84	0.14
Baseline (for ppts. with an AV3 scan)	5146	0.84	0.14
Baseline (for ppts. with an AV6 scan)	4261	0.84	0.14
Baseline (for ppts. with an AV9 scan)	673	0.84	0.12
AV3	5186	0.85	0.14
AV6	4297	0.84	0.14
AV9	676	0.82	0.13
AV3 % Change from baseline BMD[3]	5114	0.48	4.33
AV6 % Change from baseline BMD[3]	4214	-0.07	5.51
AV9 % Change from baseline BMD[3]	665	-1.92	6.29

[1] Measured in (g/cm^2).
[2] Because of technical problems, data from Birmingham are based on scans collected through October 2003 only.
[3] AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x100.

Table 5.5
Bone Mineral Density[1] Analysis: OS Participants by Race/Ethnicity

Data as of: February 29, 2004[2]

	American Indian/ Alaskan Native			Asian/Pacific Islander			Black/African American			Hispanic/Latino			White			Unknown		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan																		
Baseline	108	1.01	0.12	25	1.02	0.09	828	1.05	0.11	464	1.01	0.11	4944	1.01	0.10	46	1.01	0.12
Baseline (for ppts. with an AV3 scan)	77	1.02	0.12	22	1.03	0.09	572	1.05	0.11	323	1.01	0.10	4073	1.01	0.10	36	1.00	0.11
Baseline (for ppts. with an AV6 scan)	51	1.03	0.12	15	1.02	0.07	493	1.05	0.11	304	1.02	0.10	3338	1.01	0.10	23	0.99	0.12
AV3	81	1.03	0.13	22	1.03	0.11	580	1.06	0.12	338	1.03	0.11	4100	1.01	0.11	37	1.01	0.10
AV6	53	1.03	0.13	15	1.04	0.12	500	1.05	0.12	318	1.06	0.13	3359	1.03	0.12	24	0.99	0.13
AV3 % Change from baseline BMD[3]	77	0.70	4.45	22	-0.03	5.44	572	1.52	3.35	322	1.51	4.43	4067	0.84	3.65	36	0.42	2.92
AV6 % Change from baseline BMD[3]	51	0.83	5.88	15	1.60	6.69	493	0.01	3.90	301	3.39	6.27	3327	2.15	5.67	23	0.03	3.85
Spine Scan																		
Baseline	109	0.99	0.17	24	0.95	0.12	819	1.04	0.18	450	0.95	0.16	4800	0.97	0.17	45	0.99	0.19
Baseline (for ppts. with an AV3 scan)	77	0.99	0.15	21	0.96	0.12	576	1.04	0.17	315	0.95	0.16	3983	0.97	0.17	34	0.95	0.18
Baseline (for ppts. with an AV6 scan)	52	0.99	0.17	14	0.94	0.10	465	1.04	0.17	296	0.96	0.16	3217	0.97	0.16	23	0.97	0.23
AV3	81	1.00	0.16	21	0.96	0.12	579	1.05	0.19	328	0.95	0.16	4001	0.98	0.17	35	0.95	0.17
AV6	54	1.01	0.17	14	0.96	0.11	468	1.05	0.19	311	0.96	0.17	3231	1.00	0.18	24	1.00	0.24
AV3 % Change from baseline BMD[3]	77	0.16	5.83	21	0.42	4.57	576	1.15	5.59	314	0.28	5.38	3976	1.91	5.02	34	0.84	5.17
AV6 % Change from baseline BMD[3]	52	0.96	8.42	14	2.16	4.64	465	1.54	6.57	293	1.14	6.95	3205	3.84	6.92	23	3.09	7.29
Hip Scan																		
Baseline	109	0.87	0.15	25	0.82	0.10	827	0.93	0.15	464	0.83	0.13	4948	0.83	0.13	46	0.85	0.14
Baseline (for ppts. with an AV3 scan)	78	0.88	0.15	22	0.82	0.10	582	0.93	0.15	324	0.83	0.12	4104	0.83	0.13	36	0.83	0.12
Baseline (for ppts. with an AV6 scan)	51	0.90	0.16	15	0.79	0.08	496	0.93	0.15	308	0.84	0.12	3367	0.83	0.13	24	0.82	0.15
AV3	82	0.88	0.15	22	0.82	0.09	588	0.94	0.15	338	0.85	0.13	4119	0.83	0.13	37	0.82	0.13
AV6	53	0.89	0.17	15	0.81	0.09	502	0.91	0.15	323	0.85	0.13	3379	0.83	0.13	25	0.81	0.15
AV3 % Change from baseline BMD[3]	77	-0.36	4.85	22	0.72	4.21	582	0.36	4.00	322	1.68	4.99	4075	0.43	4.30	36	-0.81	4.76
AV6 % Change from baseline BMD[3]	50	-1.21	7.56	15	2.34	5.68	494	-2.37	4.85	304	1.24	6.25	3327	0.17	5.39	24	-1.51	6.61

[1] Measured in (g/cm^2).
[2] Because of technical problems, data from Birmingham are based on scans collected through October 2003 only.
[3] AVX % Change from baseline BMD is defined as ((AVX-Baseline)/Baseline)x100.

Table 5.6
Lost-to-Follow-up and Vital Status: OS Participants

Data as of: February 29, 2004

	OS Participants (N = 93,676) N	%
Vital Status/Participation		
Deceased	4392	4.7
Alive: Current Participation[1]	83862	89.5
Alive: Recent Participation[2]	1933	2.1
Alive: Past/Unknown Participation[3]	211	0.2
Stopped Follow-Up[4]	1773	1.9
Lost to Follow-Up[5]	1505	1.6

[1] Participants who have filled in a Form 33 within the last 15 months.
[2] Participants who last filled in a Form 33 between 15 and 24 months ago.
[3] Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 5.7
Verified Outcomes (Annualized Percentages) by Age for OS Participants

Data as of: February 29, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number enrolled	93676	12383	17323	41199	22771
Mean follow-up (months)	77.0	81.3	79.8	76.0	74.1
Cardiovascular					
CHD[1]	1818 (0.30%)	64 (0.08%)	151 (0.13%)	731 (0.28%)	872 (0.62%)
CHD death[2]	524 (0.09%)	13 (0.02%)	27 (0.02%)	170 (0.07%)	314 (0.22%)
Clinical MI	1452 (0.24%)	54 (0.06%)	132 (0.11%)	608 (0.23%)	658 (0.47%)
Angina	2382 (0.40%)	105 (0.13%)	259 (0.22%)	1107 (0.42%)	911 (0.65%)
CABG/PTCA	2485 (0.41%)	90 (0.11%)	256 (0.22%)	1183 (0.45%)	956 (0.68%)
Carotid artery disease	467 (0.08%)	24 (0.03%)	34 (0.03%)	187 (0.07%)	222 (0.16%)
Congestive heart failure	1762 (0.29%)	64 (0.08%)	138 (0.12%)	688 (0.26%)	872 (0.62%)
Stroke	1528 (0.25%)	41 (0.05%)	117 (0.10%)	585 (0.22%)	785 (0.56%)
PVD	411 (0.07%)	14 (0.02%)	36 (0.03%)	174 (0.07%)	187 (0.13%)
Coronary disease[3]	5383 (0.90%)	221 (0.26%)	514 (0.45%)	2321 (0.89%)	2327 (1.65%)
Total cardiovascular disease	7330 (1.22%)	289 (0.34%)	668 (0.58%)	3075 (1.18%)	3298 (2.34%)
Cancer					
Breast cancer	3398 (0.57%)	351 (0.42%)	611 (0.53%)	1566 (0.60%)	870 (0.62%)
Invasive breast cancer	2859 (0.48%)	286 (0.34%)	504 (0.44%)	1319 (0.51%)	750 (0.53%)
Non-invasive breast cancer	552 (0.09%)	68 (0.08%)	109 (0.09%)	254 (0.10%)	121 (0.09%)
Ovarian cancer	285 (0.05%)	30 (0.04%)	45 (0.04%)	130 (0.05%)	80 (0.06%)
Endometrial cancer[4]	464 (0.13%)	36 (0.07%)	68 (0.09%)	214 (0.14%)	146 (0.19%)
Colorectal cancer	711 (0.12%)	39 (0.05%)	80 (0.07%)	324 (0.12%)	268 (0.19%)
Other cancer[5]	3185 (0.53%)	226 (0.27%)	401 (0.35%)	1454 (0.56%)	1104 (0.78%)
Total cancer	7714 (1.28%)	666 (0.79%)	1163 (1.01%)	3534 (1.35%)	2351 (1.67%)
Fractures					
Hip fracture	784 (0.13%)	20 (0.02%)	58 (0.05%)	240 (0.09%)	466 (0.33%)
Vertebral fracture[6]	94 (0.21%)	5 (0.08%)	7 (0.08%)	33 (0.17%)	49 (0.46%)
Other fracture[5, 6]	602 (1.33%)	76 (1.14%)	97 (1.15%)	249 (1.28%)	180 (1.68%)
Total fracture[7]	1432 N/A	99 N/A	158 N/A	506 N/A	669 N/A
Deaths					
Cardiovascular deaths	1196 (0.20%)	34 (0.04%)	68 (0.06%)	378 (0.14%)	716 (0.51%)
Cancer deaths	1905 (0.32%)	105 (0.13%)	220 (0.19%)	826 (0.32%)	754 (0.54%)
Other known cause	822 (0.14%)	37 (0.04%)	86 (0.07%)	298 (0.11%)	401 (0.29%)
Unknown cause	282 (0.05%)	17 (0.02%)	25 (0.02%)	110 (0.04%)	130 (0.09%)
Not yet adjudicated	187 (0.03%)	8 (0.01%)	18 (0.02%)	80 (0.03%)	81 (0.06%)
Total death	4392 (0.73%)	201 (0.24%)	417 (0.36%)	1692 (0.65%)	2082 (1.48%)

[1] "CHD" includes clinical MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[4] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[5] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[6] For the OS, only women from three bone density clinics are used to compute the annual rates for vertebral and other fractures.
[7] Hip fractures are adjudicated at all clinics, while other fractures for OS participants are adjudicated only at a few clinics. A combined annualized percentage cannot be computed.

Table 5.7 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for OS Participants

Data as of: February 29, 2004

Outcomes	Ethnicity: American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number enrolled	421	2671	7635	3609	78016	1324
Mean follow-up (months)	72.3	74.7	72.9	69.5	77.9	74.3
Cardiovascular						
CHD[1]	10 (0.39%)	34 (0.20%)	170 (0.37%)	31 (0.15%)	1542 (0.30%)	31 (0.38%)
CHD death[2]	4 (0.16%)	11 (0.07%)	73 (0.16%)	7 (0.03%)	418 (0.08%)	11 (0.13%)
Clinical MI	7 (0.28%)	26 (0.16%)	114 (0.25%)	27 (0.13%)	1254 (0.25%)	24 (0.29%)
Angina	15 (0.59%)	37 (0.22%)	207 (0.45%)	69 (0.33%)	2031 (0.40%)	23 (0.28%)
CABG/PTCA	13 (0.51%)	42 (0.25%)	162 (0.35%)	67 (0.32%)	2168 (0.43%)	33 (0.40%)
Carotid artery disease	3 (0.12%)	4 (0.02%)	22 (0.05%)	10 (0.05%)	420 (0.08%)	8 (0.10%)
Congestive heart failure	11 (0.43%)	21 (0.13%)	186 (0.40%)	38 (0.18%)	1479 (0.29%)	27 (0.33%)
Stroke	9 (0.35%)	38 (0.23%)	155 (0.33%)	30 (0.14%)	1274 (0.25%)	22 (0.27%)
PVD	2 (0.08%)	4 (0.02%)	42 (0.09%)	5 (0.02%)	347 (0.07%)	11 (0.13%)
Coronary disease[3]	31 (1.22%)	88 (0.53%)	500 (1.08%)	131 (0.63%)	4567 (0.90%)	66 (0.81%)
Total cardiovascular disease	40 (1.58%)	131 (0.79%)	692 (1.49%)	168 (0.80%)	6195 (1.22%)	104 (1.27%)
Cancer						
Breast cancer	9 (0.35%)	72 (0.43%)	212 (0.46%)	82 (0.39%)	2989 (0.59%)	34 (0.41%)
Invasive breast cancer	8 (0.32%)	61 (0.37%)	175 (0.38%)	71 (0.34%)	2515 (0.50%)	29 (0.35%)
Non-invasive breast cancer	1 (0.04%)	11 (0.07%)	39 (0.08%)	12 (0.06%)	484 (0.10%)	5 (0.06%)
Ovarian cancer	1 (0.04%)	5 (0.03%)	16 (0.03%)	10 (0.05%)	252 (0.05%)	1 (0.01%)
Endometrial cancer[4]	0 (0.00%)	7 (0.06%)	15 (0.07%)	7 (0.06%)	426 (0.14%)	9 (0.19%)
Colorectal cancer	2 (0.08%)	11 (0.07%)	88 (0.19%)	15 (0.07%)	587 (0.12%)	8 (0.10%)
Other cancer[5]	14 (0.55%)	57 (0.34%)	205 (0.44%)	67 (0.32%)	2795 (0.55%)	47 (0.57%)
Total cancer	26 (1.02%)	146 (0.88%)	515 (1.11%)	176 (0.84%)	6758 (1.34%)	93 (1.13%)
Fractures						
Hip fracture	4 (0.16%)	9 (0.05%)	18 (0.04%)	10 (0.05%)	733 (0.14%)	10 (0.12%)
Vertebral fracture[6]	1 (0.17%)	0 (0.00%)	3 (0.05%)	2 (0.07%)	88 (0.25%)	0 (0.00%)
Other fracture[5, 6]	9 (1.50%)	3 (1.69%)	36 (0.63%)	33 (1.07%)	515 (1.46%)	6 (2.04%)
Total fracture[7]	13 N/A	12 N/A	54 N/A	44 N/A	1293 N/A	16 N/A
Deaths						
Cardiovascular deaths	9 (0.35%)	31 (0.19%)	146 (0.31%)	25 (0.12%)	965 (0.19%)	20 (0.24%)
Cancer deaths	10 (0.39%)	35 (0.21%)	164 (0.35%)	49 (0.23%)	1624 (0.32%)	23 (0.28%)
Other known cause	11 (0.43%)	16 (0.10%)	79 (0.17%)	36 (0.17%)	671 (0.13%)	9 (0.11%)
Unknown cause	2 (0.08%)	4 (0.02%)	43 (0.09%)	15 (0.07%)	216 (0.04%)	2 (0.02%)
Not yet adjudicated	1 (0.04%)	2 (0.01%)	21 (0.05%)	4 (0.02%)	156 (0.03%)	3 (0.04%)
Total death	33 (1.30%)	88 (0.53%)	453 (0.98%)	129 (0.62%)	3632 (0.72%)	57 (0.70%)

[1] "CHD" includes clinical MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[4] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[5] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[6] For the OS, only women from three bone density clinics are used to compute the annual rates for vertebral and other fractures.
[7] Hip fractures are adjudicated at all clinics, while other fractures for OS participants are adjudicated only at a few clinics. A combined annualized percentage cannot be computed.

Table 5.8
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for OS Participants who did not report a prevalent condition at baseline

Data as of: February 29, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	93676	12383	17323	41199	22771
Mean follow-up (months)	77.0	81.3	79.8	76.0	74.1
Hospitalizations					
Ever	39039 (6.50%)	3592 (4.28%)	5684 (4.93%)	17532 (6.72%)	12231 (8.69%)
Two or more	18593 (3.09%)	1405 (1.67%)	2292 (1.99%)	8300 (3.18%)	6596 (4.69%)
Other					
DVT[1]	634 (0.11%)	47 (0.06%)	75 (0.07%)	285 (0.11%)	227 (0.17%)
Pulmonary embolism	394 (0.07%)	33 (0.04%)	52 (0.05%)	174 (0.07%)	135 (0.10%)
Diabetes (treated)	4198 (0.73%)	523 (0.64%)	765 (0.69%)	1915 (0.77%)	995 (0.74%)
Gallbladder disease[2]	4856 (0.96%)	721 (0.97%)	971 (0.98%)	2186 (1.00%)	978 (0.85%)
Hysterectomy	2610 (0.74%)	370 (0.74%)	512 (0.72%)	1210 (0.80%)	518 (0.66%)
Glaucoma	6888 (1.20%)	687 (0.83%)	1053 (0.94%)	3177 (1.28%)	1971 (1.53%)
Osteoporosis	18279 (3.32%)	1794 (2.22%)	2889 (2.63%)	8454 (3.55%)	5142 (4.23%)
Osteoarthritis[3]	13444 (3.84%)	1717 (2.83%)	2418 (3.20%)	6018 (4.12%)	3291 (4.85%)
Rheumatoid arthritis	3907 (0.69%)	538 (0.67%)	751 (0.68%)	1610 (0.65%)	1008 (0.77%)
Intestinal polyps	11034 (2.03%)	1277 (1.60%)	2085 (1.93%)	5162 (2.20%)	2510 (2.07%)
Lupus	851 (0.14%)	123 (0.15%)	168 (0.15%)	376 (0.14%)	184 (0.13%)
Kidney stones[3]	1897 (0.38%)	244 (0.36%)	353 (0.38%)	805 (0.37%)	495 (0.42%)
Cataracts[3]	23015 (5.45%)	1346 (1.99%)	3273 (3.57%)	11952 (6.35%)	6444 (8.62%)
Pills for hypertension	18312 (4.27%)	2082 (2.99%)	3255 (3.62%)	8000 (4.41%)	4975 (5.64%)

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	421	2671	7635	3609	78016	1324
Mean follow-up (months)	72.3	74.7	72.9	69.5	77.9	74.3
Hospitalizations						
Ever	199 (7.84%)	702 (4.22%)	3056 (6.59%)	1147 (5.49%)	33416 (6.60%)	519 (6.33%)
Two or more	105 (4.14%)	267 (1.60%)	1460 (3.15%)	429 (2.05%)	16082 (3.18%)	250 (3.05%)
Other						
DVT[1]	3 (0.13%)	4 (0.02%)	57 (0.13%)	10 (0.05%)	552 (0.11%)	8 (0.10%)
Pulmonary embolism	1 (0.04%)	3 (0.02%)	31 (0.07%)	2 (0.01%)	353 (0.07%)	4 (0.05%)
Diabetes (treated)	43 (1.99%)	150 (0.95%)	649 (1.59%)	271 (1.39%)	3023 (0.61%)	62 (0.79%)
Gallbladder disease[2]	27 (1.36%)	65 (0.43%)	317 (0.77%)	204 (1.25%)	4174 (0.98%)	69 (1.01%)
Hysterectomy	7 (0.55%)	43 (0.40%)	106 (0.51%)	91 (0.80%)	2319 (0.77%)	44 (0.92%)
Glaucoma	42 (1.80%)	224 (1.41%)	823 (1.93%)	251 (1.27%)	5451 (1.13%)	97 (1.24%)
Osteoporosis	77 (3.32%)	558 (3.67%)	889 (2.02%)	647 (3.37%)	15830 (3.43%)	278 (3.71%)
Osteoarthritis[3]	54 (3.78%)	426 (3.64%)	1104 (4.10%)	628 (4.58%)	11026 (3.79%)	206 (4.14%)
Rheumatoid arthritis	34 (1.46%)	89 (0.56%)	574 (1.36%)	338 (1.74%)	2799 (0.58%)	73 (0.95%)
Intestinal polyps	40 (1.72%)	283 (1.90%)	887 (2.08%)	334 (1.71%)	9345 (2.04%)	145 (1.97%)
Lupus	8 (0.32%)	14 (0.08%)	82 (0.18%)	49 (0.24%)	685 (0.14%)	13 (0.16%)
Kidney stones[3]	15 (0.73%)	35 (0.25%)	219 (0.56%)	111 (0.63%)	1482 (0.36%)	35 (0.51%)
Cataracts[3]	89 (4.99%)	594 (5.14%)	1663 (4.94%)	755 (4.65%)	19581 (5.54%)	333 (5.79%)
Pills for hypertension	86 (5.32%)	496 (4.24%)	1462 (6.44%)	764 (4.88%)	15234 (4.10%)	270 (4.72%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 5.9
First Reported Verified Outcomes Before and After AV-3[1] for OS Participants

Data as of: February 29, 2004

Outcome	Number of Events	
	Before AV-3	After AV-3
Cardiovascular		
CHD[2]	758	1060
CHD death[3]	177	347
Clinical MI	638	814
Angina	1269	1113
CABG/PTCA	1164	1321
Carotid artery disease	222	245
Congestive heart failure	716	1046
Stroke	567	961
PVD	198	213
Coronary disease[4]	2580	2803
Total cardiovascular disease	3437	3893
Cancer		
Breast cancer	1593	1805
Invasive breast cancer	1335	1524
Non-invasive breast cancer	264	288
Ovarian cancer	135	150
Endometrial cancer	212	252
Colorectal cancer	331	380
Other cancer[5]	1425	1760
Total cancer	3622	4092
Fractures		
Hip fracture[6]	293	491
Vertebral fracture[6]	35	59
Other fracture[5, 6]	275	327
Total fracture[6]	592	840
Deaths		
Cardiovascular deaths	371	825
Cancer deaths	618	1287
Deaths: other known cause	222	600
Deaths: unknown cause	57	225
Deaths: not yet adjudicated	1	186
Total death	1269	3123

[1] AV-3 date is the blood draw date for participants with an AV-3 blood draw and the OS enrollment date plus 3 years for participants without an AV-3 blood draw. All participants have been enrolled for at least 3 years.
[2] "CHD" includes clinical MI and CHD death.
[3] "CHD death" includes definite and possible CHD death.
[4] "Coronary disease" includes clinical MI, Evolving Q-wave MI, Possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[5] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[6] Hip fractures are adjudicated at all clinics, while other fractures are adjudicated only at a few clinics.

Table 5.10
Counts of Participants with Self-Reported Outcomes Before and After AV-3[1]
for OS Participants who did not report a prevalent condition at baseline

Data as of: February 29, 2004

Outcome	Number of Events	
	Before AV-3	After AV-3
Ever hospitalized	19161	19878
DVT[2]	227	407
Pulmonary embolism	130	264
Diabetes (treated)	1740	2458
Gallbladder disease[3]	2138	2718
Hysterectomy	1246	1364
Glaucoma	2755	4133
Osteoporosis	8703	9576
Osteoarthritis[4]	6339	7105
Rheumatoid arthritis	1724	2183
Intestinal polyps	4397	6637
Lupus	348	503
Kidney stones[4]	646	1251
Cataracts[4]	9145	13870
Pills for hypertension	8141	10171

[1] AV-3 date is the blood draw date for participants with an AV-3 blood draw and the OS enrollment date plus 3 years for participants without an AV-3 blood draw. All participants have been enrolled for at least 3 years.
[2] Inpatient DVT only.
[3] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[4] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

6. Outcomes Processing

6.1 Overview

Most outcomes are initially ascertained by self-report on *Form 33 – Medical History Update*. CT participants complete this form every six months; OS participants complete this form every year. Those participants who report an outcome requiring documentation and adjudication are asked to complete a more detailed form (*Form 33D – Medical History Update - Detail*) that collects the information needed to request the associated medical records.

After these forms are completed and entered into the database, the CCs identify adjudication cases based on the *Form 33D* information. CCs then request hospital and related records. Once the cases are documented, clinic staff sends the charts having potential cardiovascular, cancer, and fracture outcomes to the local physician adjudicator for evaluation and classification. Key cardiovascular outcomes are further adjudicated by a central committee process. The investigators at UCSF (Steve Cummings, PI) subcontract to the CCC to adjudicate all hip fractures. Staff at the CCC code and adjudicate all cancers of major interest in the study (breast, colon, rectum, ovary, and endometrium) using standardized SEER guidelines. Outcomes for selected other diseases, such as diabetes, gallbladder disease, and hysterectomy, are collected as self-reports only.

For the first time in this report we use data from central adjudicated cases for those outcomes where 100% of all self-reports and the locally verified outcomes is centrally adjudicated in *Sections 2, 3, 4, and 5.* A detailed description of the implications can be found in *Section 6.3.*

6.2 Terminology

When a particular outcome, say MI, is investigated, all participants can be divided into five groups:

1. Those who have no self-report of an MI and have no locally confirmed MI.

2. Those who have a self-report of an MI and a locally confirmed MI. We refer to these participants' cases as *confirmed (with self-report).*

3. Those who have no self-report of an MI but do have a locally confirmed MI usually as a result of an investigation of a self-report of another outcome. We refer to these participants' cases as *confirmed (without self-report).*

4. Those who have a self-report of an MI but do not have a locally confirmed MI, and for whom all relevant adjudication cases are closed. We refer to these participants' self-reports as *denied.*

5. Those who have a self-report of an MI, but do not have a locally confirmed MI, while some of the relevant adjudication cases are still open. We refer to these participants' self-reports as *open.*

The *confirmed cases* are the cases of participants in categories 2 and 3; the *self-reports* are the cases of participants in categories 2, 4, and 5; the *closed self-reports* are the cases of participants in categories 2 and 4. For some analyses we divide the *denied* self-reports into three groups:

4a. The reports of the participants for which the self-reported outcome was denied, but for whom a related outcome (e.g., an angina based on an MI self-report) was found. We refer to those participants' self-reports as *denied - related outcome found.* For the outcome tables, we consider all cardiovascular outcomes to be related, all cancer outcomes to be related, and all fracture outcomes to be related.

4b. The reports of the participants for which the self-reported outcome was denied after review of the relevant documentation. We refer to those participants' self-reports as *denied - no (related) outcome found.*

4c. The reports of the participants for which the self-report was *denied* for *administrative reasons.* Self-reports can only be denied if they satisfy one of several narrowly defined rules. Usually this means that no documentation was obtained after several attempts over a one-year period.

6.3 Central Adjudication

The following outcomes are centrally adjudicated:

- Clinical MI, angina, CHF, CABG/PTCA, self reports of MI that are denied locally: all cases that occurred before 1/1/2001, all cases for HRT participants, and 10% of the cases that occurred after 1/1/2001 for other participants are centrally adjudicated. Note that many of the self-reports of MI that are denied locally are already centrally adjudicated because another centrally adjudicated outcome, such as CHF or angina, was found.

- Stroke, PE, DVT, and self reports of stroke, PE, and DVT that are denied locally: all cases for HRT participants are centrally adjudicated.

- Primary cancers (breast, colorectal, ovary, endometrium), hip fracture, and self-reports of primary cancer and hip fracture that are denied locally: all cases are centrally adjudicated.

- Death: all cases that occurred before 1/1/2001, all cases for CT participants, and 10% of the cases that occurred after 1/1/2001 for OS participants are centrally adjudicated.

In this report we use data from central adjudicated cases for those outcomes where 100% of all self-reports and the locally verified outcomes is centrally adjudicated in the outcomes tables in *Sections 2, 3, 4,* and *5.* In particular, those outcomes are death (and the various death classifications), breast, colorectal, endometrial, and ovarian cancer, and hip fracture for all trials, and clinical MI, stroke, PE, and DVT for the HRT trials. These central adjudicated data are supplemented with local verified outcomes for cases for which the central adjudication is not yet completed (see *Tables 6.5* and *6.6*). The main reason why we use central adjudication is that this data is thought to be of higher quality. The Morbidity and Mortality committee has mandated that all papers using outcomes that for which central adjudicated data are available on all participants should use such data.

6.4 Outcomes Data Quality

Tables 6.1 and *6.2 – Timeliness and Completeness of Local Adjudications* display the distribution of time required to locally adjudicate a self-reported outcome by month on *Form 33* for the CT and the OS, respectively. This table is based on the day on which the form was received by the clinic, which may not be the same as the day on which the form was entered in the database. Overall 97% of self-reported outcomes in the CT and 97% of the self-reported outcomes in the OS requiring adjudication have been closed. In particular, 60% of the outcomes in the CT and 61% of the outcomes in the OS have been closed within 90 days of self-report and 79% (CT) and 81% (OS) within 180 days. (Note: the fact that the percentages for the OS appear better is because most of the outcomes in 1996 and earlier, when outcomes processing was considerably slower, are CT outcomes.)

As only about a half year is left before the close-out of the CT starts, the OPMC has increased the of targeted intervention phone calls, and the CCC has send out outcomes liaisons to trouble-shoot clinics on a regular basis.

Figures 6.1 and *6.2 – Timeliness per Period of Self-Report* display Kaplan-Meier curves for the time period from reporting an outcome on *Form 33D* until the adjudication case is closed per year of self-report separately for the CT and OS. Both figures clearly show that improvements in the processing of outcomes have happened throughout the study.

Tables 6.3 and *6.4 – Agreement of Local Adjudications with Self-Reports* show condition types that the participant can indicate on *Form 33* or *Form 33D* and the fraction of time that the local adjudicator agrees with that self-report. Because of the complications of the adjudication process, it is not straightforward to define an appropriate estimate of the accuracy of individual self-reports. For example, for most outcome types, second occurrences do not need to be adjudicated, but if the participant reports a second occurrence before the first is confirmed, an adjudication case will be opened. This case will be closed without a locally confirmed outcome when the first self-report is confirmed. To circumvent this and similar problems, the unit in *Tables 6.3* and *6.4* is defined to be a *participant* rather than an outcome event. For some participants whose self-report is denied, related outcomes may be found. We also note that on *Form 33* and *Form 33D* participants report a "stroke or transient ischemic attack (TIA)," while for monitoring purposes only the outcome "stroke" is used. Thus, the number of confirmed cases in *Tables 6.3* and *6.4,* which include TIA, is substantially larger than that in some of the outcomes tables in other sections of this report.

A self-reported outcome may be denied for the following reasons: (i) the outcome did take place, but could not be verified because insufficient evidence was available to the WHI adjudicator; (ii) the outcome did not take place, but a related outcome (which may or may not be of interest to WHI) occurred; (iii) the outcome took place before enrollment in WHI; and (iv) the current self-report was a duplicate report of a previous self-report.

The accuracy of self-reports varies considerably by outcome. For many outcomes the agreement rates for the CT are a few percentage points higher than for the OS. The accuracy of cancer and fracture self-reports may be higher than that for cardiovascular disease because more cardiovascular self-reports result in a related outcome. If those related outcomes are included with the confirmed self-reports, cardiovascular outcomes have a 76% agreement rate between self-

reports and locally confirmed outcomes (84% if we exclude angina, which is probably the softest cardiovascular outcome), cancer outcomes have an agreement rate of 87% (93% for the primary cancers), and fracture outcomes have an agreement rate of 81% for the CT and OS combined.

Note that the accuracy of self-reports for *other fractures* (*other cancers*) reflects the percentage of people who reported an *other fracture* (*other cancer*) for whom any of the fractures (cancers) in the other category was found, even if the participant indicated the wrong skeletal site (cancer site).

Tables 6.5 and *6.6 – Agreement of Central Adjudications with Local Adjudications* show that there is good agreement between local and central adjudications for all outcomes. Often angina and congestive heart failure occur in conjunction with an MI. Disagreement on angina or CHF, when there is agreement about the MI is not considered very serious. Some self-reports are locally adjudicated as one type of outcome, while they are centrally adjudicated as another outcome. Data regarding such cross-classification are not shown.

We note that, thanks to the effort of the central adjudicators and the CCC cancer coders the fraction of outcomes that were called forward for central adjudication that have been centrally adjudicated has increased considerably. Now about 94% of the cardiovascular outcomes have been adjudicated and about 96% of the cancer outcomes have been centrally adjudicated.

For some of the outcomes there appears to be a large difference in agreement rate between the CT and the OS. This is an artifact. For CT participants disagreements between local and central adjudicators are further investigated. As a result of that a number of the central adjudications involved are subsequently recoded to agree with the local adjudication. The result of this second central adjudication is an apparent higher agreement rate between local and central adjudication.

Tables 6.5 and *6.6* show how many outcomes were identified by local adjudicators, but denied centrally. *Tables 6.7* and *6.8 – Source of Outcomes Identified by Central Adjudications* show outcomes that were identified by the central adjudicators, but not by the local adjudicators. Approximately 13%(CT)-20%(OS) of the MIs that were identified by central adjudicators were not found by local adjudicators. Most of these MIs were identified on cases that were called forward for "related" events, such as angina, CHF, and CABG/PTCA. Most of the cases of endometrial cancer that were identified based on a locally confirmed other outcome, were identified because of a locally confirmed case of cancer of the uterus; most of the cases of hip fracture that were identified based on a locally confirmed other outcome, were identified because of a locally confirmed case of fractures of the upper leg; and most of the cases of stroke that were identified because of a locally confirmed other outcome were identified because of a locally confirmed case of TIA. Cancer of the uterus, upper leg fractures, and TIA are reviewed centrally specifically for this reason.

Tables 6.9 and *6.10 – Agreement of Locally and Centrally Adjudicated Cause of Death.* We note that in general there is good agreement between the local and central assessment of the cause of death. For most causes the agreement is about 90%. Notable exceptions are the "other" and "unknown" categories of all types: central adjudication seems to be able to determine the cause of death more frequently than local adjudication. In this table artherosclerotic death includes both definite and possible CHD death, as early on in the study these two categories were a combined cause of death.

6.5 Outcomes Data Summary

Table 6.11 – Verified Outcomes (Annualized Percentages) by Age and Race/Ethnicity for CT Participants contains the number of verified outcomes for the major WHI outcomes categories. Since about 3% of the self-reports still need to be adjudicated, the numbers in these tables give a lower bound on the number of outcomes that currently have occurred.

Currently, for the CT we observe approximately 105% of the invasive breast cancer, 75% of the colorectal cancer and 40% of the hip fracture, and 65% of the CHD cases of what was assumed for the power calculations. Note that DVT and PE, which are only adjudicated for HRT participants, are not included in this table.

Table 6.12 – Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CT Participants contains counts of the number of self-reports for some of the WHI outcomes that are not adjudicated. As for many of the confirmed outcomes, the participants over-report (see *Tables 6.3* and *6.4)*. The numbers in these tables should be seen as upper bounds to the number of outcomes that have currently occurred. Not surprisingly, for many of the outcomes, the rates differ considerably by minority status and by age at baseline.

Similar tables for the HRT, DM, CaD, and the OS components are in the chapters about these components. Currently, the rate of fractures in the OS and CT is very similar. The rate of cardiovascular events is slightly higher and the rate of cancers is slightly lower in the CT than in the OS.

Table 6.13 – Locally Verified Other Cancers and *Table 6.14 – Locally Verified Other Fractures* split out the other cancers and other fractures for the locally verified outcomes by event type and by study. Since for OS participants other fractures are only locally verified at the three bone mineral density clinics, we provide the number of self-reported fractures for these participants. In the CT, approximately 80% of self-reported fractures are confirmed, though the location of the fracture is misreported in approximately 25-30% of cases.

6.6 Vital Status

Table 6.15 – Cause of Death (Annualized Percentages) presents the cause of death for CT and OS participants. To reduce the time that it takes before cause of death information is available on WHI participants who have passed away, clinics are encouraged to report a "temporary" cause of death for those participants for whom some, but not all, documentation related to the death has been collected. The goal is that a temporary cause is entered in the database as soon as possible, preferably within eight weeks. The cause based on the complete documentation should be entered as soon as all documents are collected. Cases for which reported unsuccessful requests for documentation have been made over a one-year period can be closed out with incomplete documentation.

During the summer of 2001, we completed the first NDI search. Results of this investigation are detailed in *Table 6.16 – Results of NDI Search.* The NDI search identified 22 women as dead, whose death had not otherwise been ascertained by WHI.

As of the February 28 database, there were 2,824 deaths in the CT and 4,392 in the OS.

Table 6.17 – Lost-to-Follow-up and Vital Status by Clinic: CT Participants displays information about the follow-up and vital status by clinic. Since 1999, clinics are regularly provided with a list of participants for whom there is no *Form 33* within the last 18 months and who are not known to be deceased. Clinics are asked to make every effort to try to locate these participants and to encourage further study participation. Some participants had information in the database that indicated that she never wanted to be contacted again by WHI. If this were the case, clinics were to verify whether this participation status was correct. If indeed a participant has expressed this opinion, she is not to be contacted again. For these participants, we will still be able to obtain limited vital status information from National Death Index (NDI) searches.

About 4.1% of the CT participants are deceased; we do not know the vital status of about 1.4% of the CT participants, and 2.6% of the participants request no further follow-up. In addition, we lack recent outcomes information on an additional 37 participants. The study design assumed that 3% per year of the participants would be lost-to-follow-up or death. As the average follow-up of participants is now 7.2 years, we note that the follow-up is much better than what was assumed in the design.

There is considerable clinic-to-clinic variation in the vital status data. The percentage of participants who are lost-to-follow-up ranges from 0.1 to 8.2% per clinic. The percentage of participants who stopped follow-up ranges from less than 0.1 to 7.8%.

Table 6.18 – Lost-to-Follow-up and Vital Status by Clinic: OS Participants contains the same information as *Table 6.17* but about the OS. For OS, the participants are considered lost-to-follow-up if we have not received a *Form 33* within the last 24 months. Approximately 3.5% of the OS participants are either lost-to-follow-up or have stopped follow-up.

Table 6.1
Timeliness and Completeness of Local Adjudications – CT Participants[1]

Data as of: February 29, 2004

Forms with conditions[2]		Number and % of forms with conditions locally adjudicated by days from Form 33 encounter date to completion of local adjudication							
Date of Form 33 encounter		≤ 90		≤ 180		Closed		Open	
	N	N	%	N	%	N	%	N	%
<= June 30 1996	3995	269	7%	781	20%	3992	100%	3	<1%
1996 July-December	1388	307	22%	714	51%	1387	100%	1	<1%
1997 January-June	2183	764	35%	1327	61%	2182	100%	1	<1%
1997 July-December	2552	981	38%	1518	59%	2551	100%	1	<1%
1998 January-June	3576	1662	46%	2773	78%	3573	100%	3	<1%
1998 July-December	4162	2356	57%	3325	80%	4160	100%	2	<1%
1999 January-June	4607	2824	61%	3797	82%	4604	100%	3	<1%
1999 July-December	4483	2867	64%	3690	82%	4481	100%	2	<1%
2000 January-June	4716	3097	66%	3953	84%	4710	100%	6	<1%
2000 July-December	4411	2979	68%	3803	86%	4406	100%	5	<1%
2001 January- June	5213	3639	70%	4532	87%	5203	100%	10	<1%
2001 July-December	4767	3228	68%	4284	90%	4759	100%	8	<1%
2002 January-June	5282	3954	75%	4761	90%	5262	100%	20	<1%
2002 July-December	5275	3977	75%	4835	92%	5218	99%	57	1%
2003 January	949	757	80%	882	93%	939	99%	10	1%
2003 February	881	685	78%	810	92%	863	98%	18	2%
2003 March	912	651	71%	830	91%	880	96%	32	4%
2003 April	929	687	74%	842	91%	905	97%	24	3%
2003 May	911	635	70%	809	89%	857	94%	54	6%
2003 June	842	627	74%	763	91%	810	96%	32	4%
2003 July	935	677	72%	843	90%	886	95%	49	5%
2003 August	915	671	73%	829	91%	847	93%	68	7%
2003 September	851	624	73%	764	90%	764	90%	87	10%
2003 October	1006	746	74%	879	87%	879	87%	127	13%
2003 November	755	545	72%	617	82%	617	82%	138	18%
2003 December	814	577	71%	577	71%	577	71%	237	29%
2004 January	960	486	51%	486	51%	486	51%	474	49%
2004 February	640	103	16%	103	16%	103	16%	537	84%
Total	68910	41375	60%	54127	79%	66901	97%	2009	3%

[1] This table is based on the day *Form 33* was received by the clinic, not on the day the form was entered in the database.
[2] Conditions are self-reported events that require additional documentation.

Table 6.2
Timeliness and Completeness of Local Adjudications – OS Participants[1]

Data as of: February 29, 2004

Forms with conditions[2]		Number and % of forms with conditions locally adjudicated by days from Form 33 encounter date to completion of local adjudication							
Date of Form 33 encounter		≤ 90		≤ 180		Closed		Open	
	N	N	%	N	%	N	%	N	%
<= June 30 1996	238	82	34%	125	53%	238	100%	0	0%
1996 July-December	1312	305	23%	698	53%	1310	100%	2	<1%
1997 January-June	2156	845	39%	1401	65%	2155	100%	1	<1%
1997 July-December	2298	709	31%	1354	59%	2297	100%	1	<1%
1998 January-June	2835	1268	45%	2036	72%	2834	100%	1	<1%
1998 July-December	3807	2001	53%	2897	76%	3805	100%	2	<1%
1999 January-June	4754	2842	60%	3922	82%	4752	100%	2	<1%
1999 July-December	4226	2519	60%	3406	81%	4224	100%	2	<1%
2000 January-June	5931	3775	64%	4886	82%	5927	100%	4	<1%
2000 July-December	4317	2819	65%	3617	84%	4306	100%	11	<1%
2001 January- June	5380	3564	66%	4584	85%	5373	100%	7	<1%
2001 July-December	4713	3124	66%	4128	88%	4698	100%	15	<1%
2002 January - June	5768	4106	71%	5135	89%	5737	99%	31	1%
2002 July-December	4925	3504	71%	4328	88%	4843	98%	82	2%
2003 January	902	705	78%	833	92%	887	98%	15	2%
2003 February	895	687	77%	823	92%	878	98%	17	2%
2003 March	972	690	71%	891	92%	946	97%	26	3%
2003 April	1101	793	72%	984	89%	1055	96%	46	4%
2003 May	921	597	65%	803	87%	869	94%	52	6%
2003 June	1014	722	71%	898	89%	954	94%	60	6%
2003 July	1125	789	70%	992	88%	1040	92%	85	8%
2003 August	972	699	72%	864	89%	881	91%	91	9%
2003 September	956	707	74%	848	89%	848	89%	108	11%
2003 October	948	643	68%	808	85%	808	85%	140	15%
2003 November	611	444	73%	490	80%	490	80%	121	20%
2003 December	703	506	72%	506	72%	506	72%	197	28%
2004 January	887	402	45%	402	45%	402	45%	485	55%
2004 February	747	91	12%	91	12%	91	12%	656	88%
Total	65414	39938	61%	52750	81%	63154	97%	2260	3%

[1] This table is based on the day *Form 33* was received by the clinic, not on the day the form was entered in the database.
[2] Conditions are self-reported events that require additional documentation.

Figure 6.1 Clinical Trial Timeliness per Period of Self-Report

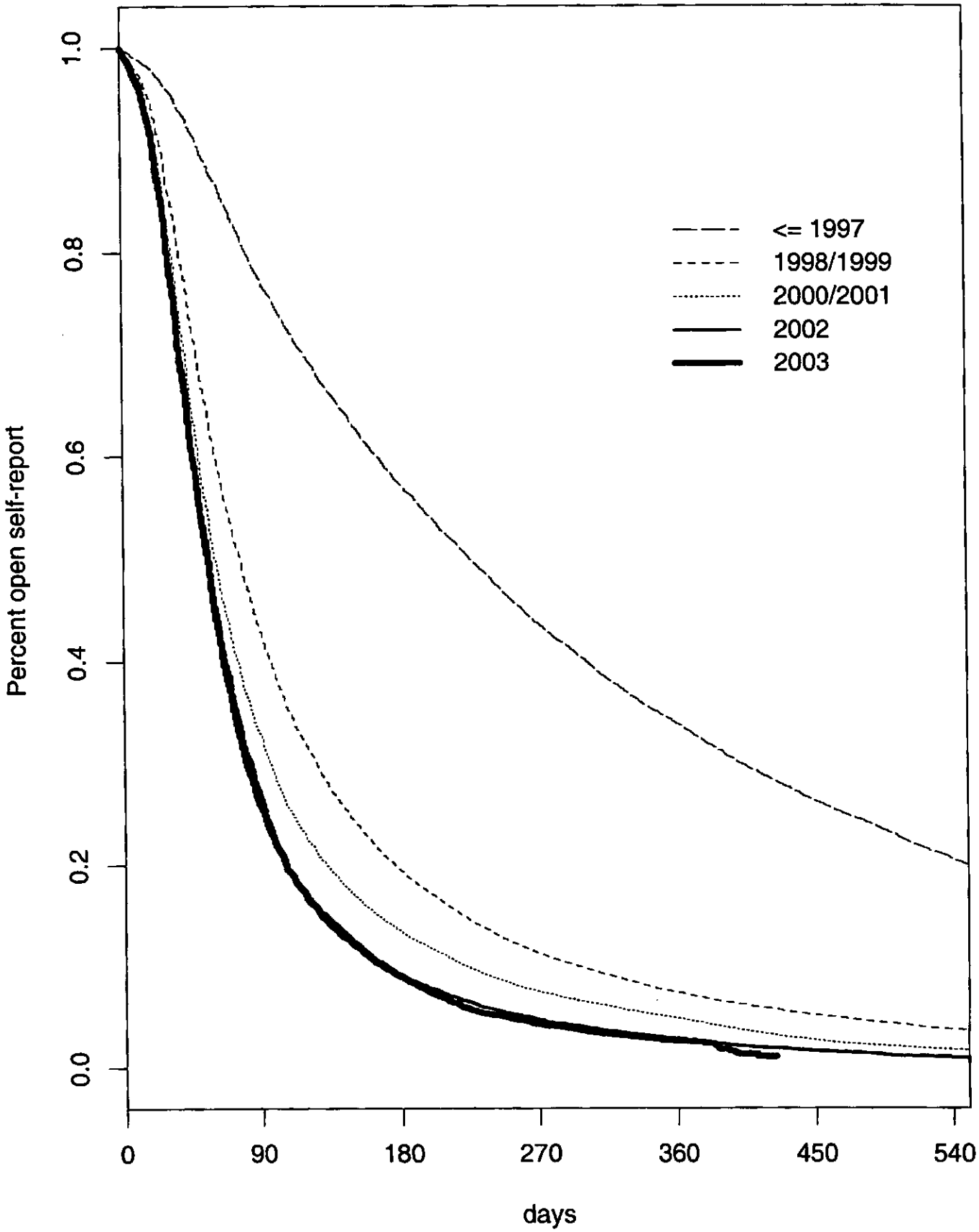


Figure 6.2 Observational Study Timeliness per Period of Self-Report

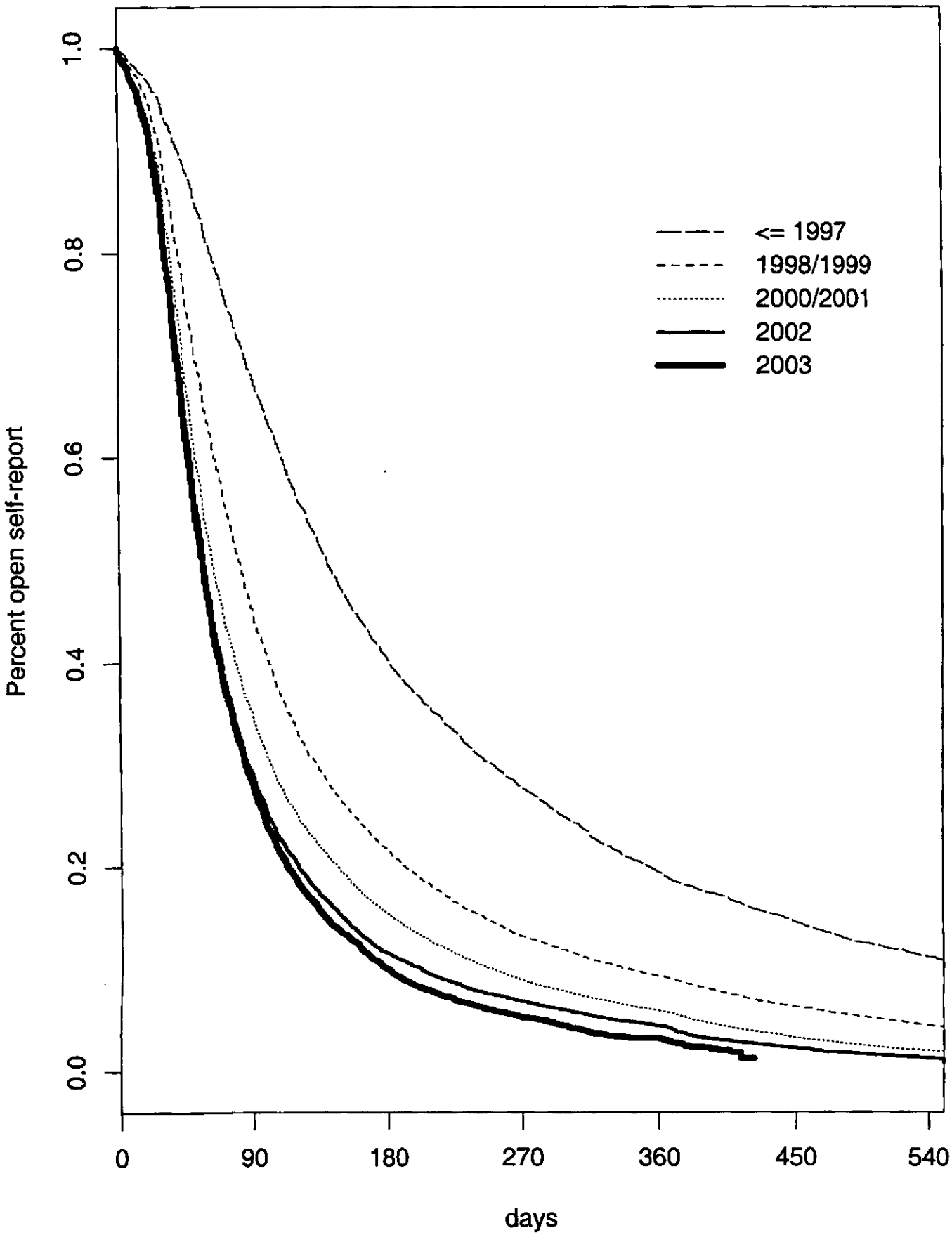


Table 6.3
Agreement of the Local Adjudications with Self-Reports — CT Participants

Data as of: February 29, 2004

	Participants with a self-report	Closed		Confirmed		Denied – related outcome found		Denied – no outcome found		Administrative denials	
		N	%	N	%[1]	N	%[1]	N	%[1]	N	%[1]
Cardiovascular											
Clinical MI	1222	1158	95%	822	(71%)	182	(16%)	139	(12%)	15	(1%)
Angina[2]	2309	2223	96%	1062	(48%)	99	(4%)	1023	(46%)	39	(2%)
Congestive heart failure	849	810	95%	600	(74%)	48	(6%)	152	(19%)	10	(1%)
CABG/PTCA	2719	2598	96%	2062	(79%)	218	(8%)	289	(11%)	29	(1%)
Carotid artery disease[3]	366	349	95%	297	(85%)	27	(8%)	21	(6%)	4	(1%)
Stroke/TIA[4]	2038	1958	96%	1509	(77%)	91	(5%)	325	(17%)	33	(2%)
PVD	261	254	97%	150	(59%)	32	(13%)	67	(26%)	5	(2%)
DVT[5]	404	386	96%	263	(68%)	54	(14%)	61	(16%)	8	(2%)
Pulmonary embolism[5]	200	196	98%	168	(86%)	10	(5%)	17	(9%)	1	(1%)
Cancers											
Breast cancer	2485	2400	97%	2318	(97%)	1	(<1%)	67	(3%)	14	(1%)
Ovarian cancer	235	220	94%	162	(74%)	42	(19%)	11	(5%)	5	(2%)
Endometrial cancer	293	286	98%	226	(79%)	35	(12%)	22	(8%)	3	(1%)
Colorectal cancer	665	640	96%	554	(87%)	41	(6%)	43	(7%)	2	(<1%)
Other cancer[6]	2789	2659	95%	2013	(76%)	139	(5%)	459	(17%)	48	(2%)
Fractures											
Hip fracture	644	604	94%	494	(82%)	47	(8%)	58	(10%)	5	(1%)
Vertebral fracture	986	933	95%	521	(56%)	40	(4%)	344	(37%)	28	(3%)
Other fracture	7847	7600	97%	6249	(82%)	85	(1%)	1075	(14%)	191	(3%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI is not adjudicated. In particular, 271 such self-reports of angina are excluded from this table.
[3] Carotid artery disease that is self-reported after a confirmed stroke is not adjudicated. In particular, 10 such self- reports of carotid artery disease are excluded from this table.
[4] Stroke and TIA have a combined self-report. Only stroke is monitored. There were 450 participants who reported stroke/TIA for whom only TIA was confirmed.
[5] HRT participants only.
[6] Excludes non-melanoma skin cancer.

Table 6.4
Agreement of the Local Adjudications with Self-Reports — OS Participants

Data as of: February 29, 2004

	Participants with a self-report	Closed		Confirmed		Denied – related outcome found		Denied – no outcome found		Administrative denials	
		N	%	N	%[1]	N	%[1]	N	%[1]	N	%[1]
Cardiovascular											
Clinical MI	1190	1130	95%	761	(67%)	192	(17%)	153	(14%)	24	(2%)
Angina[2]	2716	2598	96%	1155	(44%)	168	(6%)	1215	(47%)	60	(2%)
Congestive heart failure	1034	982	95%	741	(75%)	56	(6%)	166	(17%)	19	(2%)
CABG/PTCA	3028	2898	96%	2242	(77%)	267	(9%)	339	(12%)	50	(2%)
Carotid artery disease[3]	428	413	96%	341	(83%)	34	(8%)	33	(8%)	5	(1%)
Stroke/TIA[4]	2475	2353	95%	1732	(74%)	100	(4%)	455	(19%)	66	(3%)
PVD	366	348	95%	208	(60%)	41	(12%)	92	(26%)	7	(2%)
Cancers											
Breast cancer	3580	3426	96%	3147	(92%)	18	(1%)	209	(6%)	52	(2%)
Ovarian cancer	320	308	96%	218	(71%)	51	(17%)	37	(12%)	2	(1%)
Endometrial cancer	396	379	96%	291	(77%)	54	(14%)	27	(7%)	7	(2%)
Colorectal	772	737	95%	618	(84%)	44	(6%)	63	(9%)	12	(2%)
Other cancer[5]	3786	3587	95%	2488	(69%)	253	(7%)	752	(21%)	94	(3%)
Fractures											
Hip fracture	868	812	94%	646	(80%)	9	(1%)	136	(17%)	21	(3%)
Vertebral fracture	126	120	95%	77	(64%)	6	(5%)	31	(26%)	6	(5%)
Other fracture	847	838	99%	621	(74%)	17	(2%)	164	(20%)	36	(4%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 282 such self-reports of angina are excluded from this table.
[3] Carotid artery disease that is self-reported after a confirmed stroke is not adjudicated. In particular, 8 such self-reports of carotid artery disease are excluded from this table.
[4] Stroke and TIA have a combined self-report. Only stroke is monitored. There were 554 participants who reported stroke/TIA for whom only TIA was confirmed.
[5] Excludes non-melanoma skin cancer.

Table 6.5
Agreement of Central Adjudications with Local Adjudications — CT Participants

Data as of: February 29, 2004

	Locally confirmed N	Called forward for central adjudication N	%[1]	Centrally adjudicated N	%[2]	In agreement N	%[3]
Cardiovascular							
Clinical MI	1340	986	74%	950	96%	853	90%
Angina[4]	2082	1576	76%	1532	97%	1184	77%
Congestive heart failure	1329	958	72%	900	94%	702	78%
CABG/PTCA	2219	1621	73%	1566	97%	1521	97%
DVT[5]	345	345	100%	328	95%	317	97%
Pulmonary embolism[5]	225	225	100%	215	96%	209	97%
Stroke[6]	1238	592	48%	557	94%	508	91%
Cancers							
Breast cancer	2345	2345	100%	2274	97%	2267	100%
Invasive	1838	1838	100%	1781	97%	1743	98%
Non-invasive	507	507	100%	493	97%	425	86%
Ovarian cancer	198	198	100%	189	95%	152	80%
Endometrial cancer	288	288	100%	272	94%	261	96%
Colorectal cancer	612	612	100%	590	96%	571	97%
Fractures							
Hip fracture	599	599	100%	550	92%	515	94%

[1] Percentage is relative to locally confirmed cases.
[2] Percentage is relative to cases called forward for central adjudication.
[3] Percentage is relative to centrally adjudicated cases.
[4] Participants with a confirmed MI no longer require adjudication of angina.
[5] HRT only.
[6] Stroke is locally adjudicated for the entire CT but only centrally adjudicated for HRT participants.

Table 6.6
Agreement of Central Adjudications with Local Adjudications — OS Participants

Data as of: February 29, 2004

	Locally confirmed N	Called forward for central adjudication N	%[1]	Centrally adjudicated N	%[2]	In agreement N	%[3]
Cardiovascular							
Clinical MI	1452	733	50%	719	98%	589	82%
Angina[4]	2382	1403	59%	1384	99%	1091	79%
Congestive heart failure	1762	841	48%	817	97%	653	80%
CABG/PTCA	2485	1320	53%	1298	98%	1241	96%
Cancers							
Breast cancer	3243	3243	100%	3137	97%	3078	98%
Invasive	2654	2654	100%	2558	96%	2447	96%
Non-Invasive	589	589	100%	579	98%	466	80%
Ovarian cancer	270	270	100%	258	96%	219	85%
Endometrial cancer	418	418	100%	397	95%	373	94%
Colorectal cancer	691	691	100%	671	97%	634	94%
Fractures							
Hip fracture	801	801	100%	750	94%	721	96%

[1] Percentage is relative to locally confirmed cases.
[2] Percentage is relative to cases called forward for central adjudication.
[3] Percentage is relative to centrally adjudicated cases.
[4] Participants with a confirmed MI no longer require adjudication of angina.

Table 6.7
Source of Outcomes Identified by Central Adjudications – CT Participants

Data as of: February 29, 2004

	Centrally confirmed N	Reason for central investigation						Denied self-reports reviewed by CCC N
		Locally confirmed same outcome N	%	Locally confirmed other outcome N	%	Self-report but no outcome found N	%	
Cardiovascular								
Clinical MI	964	837	87%	120	12%	7	1%	115
Angina	1482	1170	79%	291	20%	21	1%	N/A
Congestive heart failure	812	684	84%	121	15%	7	1%	N/A
CABG/PTCA	1565	1503	96%	58	4%	4	<1%	N/A
DVT	329	314	95%	8	2%	7	2%	81
Pulmonary embolism	220	209	95%	5	2%	6	3%	17
Stroke	555	501	90%	36	6%	18	3%	304
Cancers								
Breast cancer	2281	2272	100%	3	<1%	6	<1%	87
Ovarian cancer	163	152	93%	8	5%	3	2%	25
Endometrial cancer	285	260	91%	24	8%	1	<1%	27
Colorectal cancer	583	570	98%	5	1%	8	1%	67
Fractures								
Hip fracture	535	515	96%	11	2%	9	2%	71

Table 6.8
Source of Outcomes Identified by Central Adjudications – OS Participants

Data as of: February 29, 2004

	Centrally confirmed N	Reason for central investigation: Locally confirmed same outcome N	%	Locally confirmed other outcome N	%	Self-report but no outcome found N	%	Denied self-reports reviewed by CCC N
Cardiovascular								
Clinical MI	722	576	80%	139	19%	7	1%	80
Angina	1358	1098	81%	247	18%	13	1%	N/A
Congestive heart failure	736	644	88%	88	12%	4	1%	N/A
CABG/PTCA	1282	1222	95%	53	4%	7	1%	N/A
Cancers								
Breast cancer	3106	3082	99%	3	<1%	21	1%	169
Ovarian cancer	230	219	95%	8	3%	3	1%	50
Endometrial cancer	427	372	87%	49	11%	6	1%	37
Colorectal cancer	644	634	98%	4	1%	6	1%	92
Fractures								
Hip fracture	731	721	99%	2	<1%	8	1%	102

Table 6.9
Agreement of Locally and Centrally Adjudicated Cause of Death for All CT Participants

Data as of: February 29, 2004

	Closed Local[1]	Closed Central N	%	Confirmed Cause N	%[2]	Related Cause N	%[2]	Unrelated Cause N	%[2]
Final adjudicated death	2486	2291	92%	2009	(88%)	145	(6%)	137	(6%)
Cardiovascular									
Atherosclerotic cardiac[3]	388	355	91%	326	(92%)	16	(5%)	13	(4%)
Cerebrovascular	182	169	93%	157	(93%)	5	(3%)	7	(4%)
Pulmonary embolism	18	14	78%	14	(100%)	0	(0%)	0	(0%)
Other cardiovascular	139	125	90%	74	(59%)	33	(26%)	18	(14%)
Unknown cardiovascular	33	33	100%	5	(15%)	21	(64%)	7	(21%)
Total cardiovascular deaths	760	696	92%	576	(83%)	75	(11%)	45	(6%)
Cancer									
Breast cancer	60	52	87%	51	(98%)	1	(2%)	0	(0%)
Ovarian cancer	94	87	93%	78	(90%)	8	(9%)	1	(1%)
Endometrial cancer	10	10	100%	9	(90%)	1	(10%)	0	(0%)
Colorectal cancer	119	111	93%	110	(99%)	0	(0%)	1	(1%)
Other cancer	837	787	94%	756	(96%)	23	(3%)	8	(1%)
Unknown cancer site	47	45	96%	32	(71%)	12	(27%)	1	(2%)
Total cancer deaths	1167	1092	94%	1036	(95%)	45	(4%)	11	(1%)
Accident/injury									
Homicide	5	5	100%	4	(80%)	1	(20%)	0	(0%)
Accident	63	59	94%	54	(92%)	4	(7%)	1	(2%)
Suicide	11	11	100%	11	(100%)	0	(0%)	0	(0%)
Other injury	7	7	100%	1	(14%)	4	(57%)	2	(29%)
Total accidental deaths	86	82	95%	70	(85%)	9	(11%)	3	(4%)
Other									
Other known cause	394	349	89%	292	(84%)	5	(1%)	52	(15%)
Unknown cause	79	72	91%	35	(49%)	11	(15%)	26	(36%)
Total deaths - other causes	473	421	89%	327	(78%)	16	(4%)	78	(19%)

[1] Excludes temporary adjudications.
[2] Percentages are relative to closed central.
[3] "Atherosclerotic cardiac" combines definite and possible CHD death.

Table 6.10
Agreement of Locally and Centrally Adjudicated Cause of Death for <u>All OS Participants</u>

Data as of: February 29, 2004

	Closed Local[1]	Closed Central N	Closed Central %	Confirmed Cause N	Confirmed Cause %[2]	Related Cause N	Related Cause %[2]	Unrelated Cause N	Unrelated Cause %[2]
Final adjudicated death	3879	2158	56%	1742	(81%)	179	(8%)	237	(11%)
Cardiovascular									
Atherosclerotic cardiac[3]	505	293	58%	233	(80%)	21	(7%)	39	(13%)
Cerebrovascular	310	146	47%	125	(86%)	5	(3%)	16	(11%)
Pulmonary embolism	32	14	44%	10	(71%)	0	(0%)	4	(29%)
Other cardiovascular	236	146	62%	64	(44%)	57	(39%)	25	(17%)
Unknown cardiovascular	50	27	54%	1	(4%)	18	(67%)	8	(30%)
Total cardiovascular deaths	1133	626	55%	433	(69%)	101	(16%)	92	(15%)
Cancer									
Breast cancer	260	137	53%	128	(93%)	5	(4%)	4	(3%)
Ovarian cancer	129	71	55%	65	(92%)	4	(6%)	2	(3%)
Endometrial cancer	35	18	51%	12	(67%)	6	(33%)	0	(0%)
Colorectal cancer	148	88	59%	81	(92%)	3	(3%)	4	(5%)
Other cancer	1153	675	59%	627	(93%)	22	(3%)	26	(4%)
Unknown cancer site	98	63	64%	44	(70%)	17	(27%)	2	(3%)
Total cancer deaths	1823	1052	58%	957	(91%)	57	(5%)	38	(4%)
Accident/injury									
Homicide	7	5	71%	5	(100%)	0	(0%)	0	(0%)
Accident	77	54	70%	46	(85%)	2	(4%)	6	(11%)
Suicide	20	17	85%	14	(82%)	1	(6%)	2	(12%)
Other injury	8	3	38%	2	(67%)	1	(33%)	0	(0%)
Total accidental deaths	112	79	71%	67	(85%)	4	(5%)	8	(10%)
Other									
Other known cause	665	314	47%	247	(79%)	5	(2%)	62	(20%)
Unknown cause	146	87	60%	38	(44%)	12	(14%)	37	(43%)
Total deaths - other causes	811	401	49%	285	(71%)	17	(4%)	99	(25%)

[1] Excludes temporary adjudications.
[2] Percentages are relative to closed central.
[3] "Atherosclerotic cardiac" combines definite and possible CHD death.

Table 6.11
Verified Outcomes (Annualized Percentages) by Age for CT Participants

Data as of: February 29, 2004

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	68132		9188		14662		31392		12890	
Mean follow-up (months)	83.7		90.2		86.4		82.0		80.2	
Cardiovascular										
CHD[1]	1727	(0.36%)	91	(0.13%)	188	(0.18%)	788	(0.37%)	660	(0.77%)
CHD death[2]	450	(0.09%)	19	(0.03%)	38	(0.04%)	186	(0.09%)	207	(0.24%)
Total MI[3]	1421	(0.30%)	75	(0.11%)	158	(0.15%)	657	(0.31%)	531	(0.62%)
Clinical MI	1348	(0.28%)	68	(0.10%)	151	(0.14%)	624	(0.29%)	505	(0.59%)
Evolving Q-wave MI[4]	75	(0.02%)	7	(0.01%)	7	(0.01%)	35	(0.02%)	26	(0.03%)
Possible evolving Q-wave MI[4]	327	(0.07%)	33	(0.05%)	47	(0.04%)	140	(0.07%)	107	(0.12%)
Angina	2082	(0.44%)	106	(0.15%)	279	(0.26%)	1051	(0.49%)	646	(0.75%)
CABG/PTCA	2219	(0.47%)	100	(0.14%)	269	(0.25%)	1129	(0.53%)	721	(0.84%)
Carotid artery disease	374	(0.08%)	10	(0.01%)	40	(0.04%)	189	(0.09%)	135	(0.16%)
Congestive heart failure	1329	(0.28%)	63	(0.09%)	139	(0.13%)	568	(0.26%)	559	(0.65%)
Stroke	1288	(0.27%)	47	(0.07%)	121	(0.11%)	590	(0.27%)	530	(0.62%)
PVD	329	(0.07%)	14	(0.02%)	36	(0.03%)	156	(0.07%)	123	(0.14%)
CHD[1]/Possible evolving Q-wave MI	2037	(0.43%)	124	(0.18%)	234	(0.22%)	921	(0.43%)	758	(0.88%)
Coronary disease[5]	4880	(1.03%)	267	(0.39%)	602	(0.57%)	2336	(1.09%)	1675	(1.95%)
Total cardiovascular disease	6389	(1.34%)	322	(0.47%)	752	(0.71%)	3064	(1.43%)	2251	(2.61%)
Cancer										
Breast cancer	2357	(0.50%)	260	(0.38%)	501	(0.47%)	1126	(0.52%)	470	(0.55%)
Invasive breast cancer	1883	(0.40%)	192	(0.28%)	411	(0.39%)	897	(0.42%)	383	(0.44%)
Non-invasive breast cancer	489	(0.10%)	70	(0.10%)	93	(0.09%)	236	(0.11%)	90	(0.10%)
Ovary cancer	197	(0.04%)	17	(0.02%)	41	(0.04%)	92	(0.04%)	47	(0.05%)
Endometrial cancer[6]	301	(0.06%)	29	(0.04%)	65	(0.06%)	149	(0.07%)	58	(0.07%)
Colorectal cancer	616	(0.13%)	35	(0.05%)	86	(0.08%)	314	(0.15%)	181	(0.21%)
Other cancer[7]	2410	(0.51%)	189	(0.27%)	390	(0.37%)	1175	(0.55%)	656	(0.76%)
Total cancer	5662	(1.19%)	514	(0.74%)	1046	(0.99%)	2742	(1.28%)	1360	(1.58%)
Fractures										
Hip fracture	584	(0.12%)	13	(0.02%)	37	(0.04%)	208	(0.10%)	326	(0.38%)
Vertebral fracture	634	(0.13%)	20	(0.03%)	67	(0.06%)	271	(0.13%)	276	(0.32%)
Other fracture[7]	6528	(1.37%)	773	(1.12%)	1203	(1.14%)	3056	(1.42%)	1496	(1.74%)
Total fracture	7434	(1.56%)	802	(1.16%)	1288	(1.22%)	3403	(1.59%)	1941	(2.25%)
Deaths										
Cardiovascular deaths	824	(0.17%)	29	(0.04%)	62	(0.06%)	336	(0.16%)	397	(0.46%)
Cancer deaths	1246	(0.26%)	70	(0.10%)	171	(0.16%)	602	(0.28%)	403	(0.47%)
Other known cause	489	(0.10%)	26	(0.04%)	55	(0.05%)	211	(0.10%)	197	(0.23%)
Unknown cause	133	(0.03%)	6	(0.01%)	13	(0.01%)	62	(0.03%)	52	(0.06%)
Not yet adjudicated	132	(0.03%)	12	(0.02%)	12	(0.01%)	49	(0.02%)	59	(0.07%)
Total death	2824	(0.59%)	143	(0.21%)	313	(0.30%)	1260	(0.59%)	1108	(1.29%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 6.11 (continued)
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for CT Participants

Data as of: February 29, 2004

Outcome	Race/Ethnicity					
	American Indian/Alaska n Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	292	1519	6983	2875	55525	938
Mean follow-up (months)	81.3	80.2	82.4	79.5	84.3	79.6
Cardiovascular						
CHD[1]	7 (0.35%)	21 (0.21%)	185 (0.39%)	35 (0.18%)	1452 (0.37%)	27 (0.43%)
CHD death[2]	2 (0.10%)	7 (0.07%)	78 (0.16%)	8 (0.04%)	348 (0.09%)	7 (0.11%)
Total MI[3]	6 (0.30%)	19 (0.19%)	131 (0.27%)	29 (0.15%)	1213 (0.31%)	23 (0.37%)
Clinical MI	6 (0.30%)	17 (0.17%)	127 (0.26%)	29 (0.15%)	1148 (0.29%)	21 (0.34%)
Evolving Q-wave MI[4]	0 (0.00%)	2 (0.02%)	4 (0.01%)	0 (0.00%)	67 (0.02%)	2 (0.03%)
Possible evolving Q-wave MI[4]	2 (0.10%)	9 (0.09%)	34 (0.07%)	12 (0.06%)	267 (0.07%)	3 (0.05%)
Angina	8 (0.40%)	28 (0.28%)	252 (0.53%)	65 (0.34%)	1702 (0.44%)	27 (0.43%)
CABG/PTCA	8 (0.40%)	19 (0.19%)	203 (0.42%)	54 (0.28%)	1910 (0.49%)	25 (0.40%)
Carotid artery disease	3 (0.15%)	2 (0.02%)	25 (0.05%)	3 (0.02%)	336 (0.09%)	5 (0.08%)
Congestive heart failure	4 (0.20%)	12 (0.12%)	197 (0.41%)	37 (0.19%)	1062 (0.27%)	17 (0.27%)
Stroke	7 (0.35%)	28 (0.28%)	168 (0.35%)	34 (0.18%)	1032 (0.26%)	19 (0.31%)
PVD	3 (0.15%)	3 (0.03%)	47 (0.10%)	4 (0.02%)	269 (0.07%)	3 (0.05%)
CHD[1]/Possible evolving Q-wave MI	9 (0.45%)	29 (0.29%)	218 (0.45%)	46 (0.24%)	1705 (0.44%)	30 (0.48%)
Coronary disease[5]	18 (0.91%)	61 (0.60%)	583 (1.22%)	133 (0.70%)	4020 (1.03%)	65 (1.04%)
Total cardiovascular disease	27 (1.36%)	89 (0.88%)	758 (1.58%)	170 (0.89%)	5260 (1.35%)	85 (1.37%)
Cancer						
Breast cancer	6 (0.30%)	58 (0.57%)	184 (0.38%)	62 (0.33%)	2023 (0.52%)	24 (0.39%)
Invasive breast cancer	6 (0.30%)	44 (0.43%)	141 (0.29%)	51 (0.27%)	1621 (0.42%)	20 (0.32%)
Non-invasive breast cancer	0 (0.00%)	14 (0.14%)	44 (0.09%)	11 (0.06%)	416 (0.11%)	4 (0.06%)
Ovary cancer	1 (0.05%)	3 (0.03%)	14 (0.03%)	4 (0.02%)	171 (0.04%)	4 (0.06%)
Endometrial cancer[6]	1 (0.05%)	3 (0.03%)	17 (0.04%)	9 (0.05%)	266 (0.07%)	5 (0.08%)
Colorectal cancer	5 (0.25%)	11 (0.11%)	63 (0.13%)	23 (0.12%)	504 (0.13%)	10 (0.16%)
Other cancer[7]	9 (0.45%)	35 (0.34%)	173 (0.36%)	61 (0.32%)	2105 (0.54%)	27 (0.43%)
Total cancer	22 (1.11%)	106 (1.04%)	434 (0.90%)	150 (0.79%)	4884 (1.25%)	66 (1.06%)
Fractures						
Hip fracture	1 (0.05%)	4 (0.04%)	16 (0.03%)	9 (0.05%)	549 (0.14%)	5 (0.08%)
Vertebral fracture	2 (0.10%)	12 (0.12%)	9 (0.02%)	8 (0.04%)	595 (0.15%)	8 (0.13%)
Other fracture[7]	23 (1.16%)	102 (1.00%)	369 (0.77%)	174 (0.91%)	5787 (1.48%)	73 (1.17%)
Total fracture	25 (1.26%)	117 (1.15%)	390 (0.81%)	186 (0.98%)	6633 (1.70%)	83 (1.33%)
Deaths						
Cardiovascular deaths	5 (0.25%)	14 (0.14%)	127 (0.26%)	13 (0.07%)	656 (0.17%)	9 (0.14%)
Cancer deaths	7 (0.35%)	20 (0.20%)	110 (0.23%)	38 (0.20%)	1056 (0.27%)	15 (0.24%)
Other known cause	7 (0.35%)	5 (0.05%)	58 (0.12%)	8 (0.04%)	408 (0.10%)	3 (0.05%)
Unknown cause	2 (0.10%)	2 (0.02%)	19 (0.04%)	5 (0.03%)	101 (0.03%)	4 (0.06%)
Not yet adjudicated	0 (0.00%)	2 (0.02%)	11 (0.02%)	5 (0.03%)	112 (0.03%)	2 (0.03%)
Total death	21 (1.06%)	43 (0.42%)	325 (0.68%)	69 (0.36%)	2333 (0.60%)	33 (0.53%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 6.12
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CT Participants who did not report a prevalent condition at baseline

Data as of: February 29, 2004

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68132	9188	14662	31392	12890
Mean follow-up (months)	83.7	90.2	86.4	82.0	80.2
Hospitalizations					
Ever	31259 (6.57%)	3098 (4.48%)	5574 (5.28%)	14914 (6.95%)	7673 (8.91%)
Two or more	16206 (3.41%)	1349 (1.95%)	2562 (2.43%)	7732 (3.60%)	4563 (5.30%)
Other					
DVT[1]	700 (0.15%)	40 (0.06%)	100 (0.10%)	320 (0.15%)	240 (0.29%)
Pulmonary embolism	431 (0.09%)	29 (0.04%)	59 (0.06%)	220 (0.10%)	123 (0.14%)
Diabetes (treated)	4476 (0.99%)	609 (0.91%)	931 (0.92%)	2081 (1.02%)	855 (1.05%)
Gallbladder disease[2]	4670 (1.17%)	668 (1.09%)	1067 (1.18%)	2179 (1.23%)	756 (1.09%)
Hysterectomy	1838 (0.66%)	239 (0.60%)	398 (0.61%)	884 (0.72%)	317 (0.66%)
Glaucoma	6470 (1.42%)	618 (0.91%)	1237 (1.20%)	3138 (1.53%)	1477 (1.86%)
Osteoporosis	13059 (2.91%)	1255 (1.85%)	2271 (2.22%)	6381 (3.17%)	3152 (4.10%)
Osteoarthritis[3]	11557 (5.45%)	1620 (3.15%)	2579 (3.57%)	5289 (4.22%)	2069 (4.78%)
Rheumatoid arthritis	3499 (0.77%)	461 (0.69%)	775 (0.76%)	1594 (0.78%)	669 (0.82%)
Intestinal polyps	9128 (2.07%)	1072 (1.60%)	1886 (1.88%)	4582 (2.31%)	1588 (2.08%)
Lupus	622 (0.13%)	94 (0.14%)	142 (0.13%)	286 (0.13%)	100 (0.12%)
Kidney stones[3]	1555 (0.55%)	204 (0.37%)	322 (0.37%)	737 (0.41%)	292 (0.40%)
Cataracts[3]	18890 (7.34%)	1166 (2.10%)	3078 (3.60%)	10315 (6.38%)	4331 (8.63%)
Pills for hypertension	15639 (4.68%)	1932 (3.46%)	3244 (4.03%)	7317 (5.02%)	3146 (6.01%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	292	1519	6983	2875	55525	938
Mean follow-up (months)	81.3	80.2	82.4	79.5	84.3	79.6
Hospitalizations						
Ever	132 (6.67%)	478 (4.71%)	3230 (6.73%)	1065 (5.59%)	25953 (6.65%)	401 (6.45%)
Two or more	83 (4.19%)	204 (2.01%)	1736 (3.62%)	498 (2.61%)	13473 (3.45%)	212 (3.41%)
Other						
DVT[1]	2 (0.10%)	1 (0.01%)	68 (0.15%)	10 (0.05%)	611 (0.16%)	8 (0.13%)
Pulmonary embolism	4 (0.20%)	2 (0.02%)	41 (0.09%)	3 (0.02%)	376 (0.10%)	5 (0.08%)
Diabetes (treated)	22 (1.23%)	123 (1.29%)	793 (1.87%)	294 (1.65%)	3177 (0.84%)	67 (1.15%)
Gallbladder disease[2]	20 (1.38%)	73 (0.79%)	369 (0.86%)	212 (1.46%)	3927 (1.21%)	69 (1.30%)
Hysterectomy	5 (0.57%)	32 (0.49%)	113 (0.54%)	61 (0.57%)	1614 (0.69%)	13 (0.36%)
Glaucoma	33 (1.76%)	131 (1.34%)	858 (1.93%)	279 (1.52%)	5084 (1.35%)	85 (1.46%)
Osteoporosis	59 (3.14%)	337 (3.50%)	740 (1.60%)	543 (3.06%)	11197 (3.05%)	183 (3.15%)
Osteoarthritis[3]	60 (0.12%)	277 (0.38%)	1136 (0.91%)	581 (1.34%)	9324 (5.38%)	179 (6.61%)
Rheumatoid arthritis	24 (1.35%)	68 (0.70%)	599 (1.35%)	318 (1.75%)	2428 (0.65%)	62 (1.05%)
Intestinal polyps	48 (2.64%)	191 (2.05%)	963 (2.15%)	323 (1.77%)	7484 (2.07%)	119 (2.08%)
Lupus	5 (0.26%)	9 (0.09%)	82 (0.17%)	30 (0.16%)	488 (0.13%)	8 (0.13%)
Kidney stones[3]	12 (0.02%)	36 (0.04%)	149 (0.08%)	81 (0.11%)	1256 (0.54%)	21 (0.58%)
Cataracts[3]	79 (0.14%)	376 (0.44%)	1739 (1.08%)	712 (1.42%)	15730 (7.49%)	254 (7.66%)
Pills for hypertension	68 (5.29%)	337 (4.88%)	1545 (6.45%)	719 (5.05%)	12773 (4.50%)	197 (4.79%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 6.13
Locally Verified Other Cancers (Annualized Percentages): CT and OS Participants

Data as of: February 29, 2004

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	83.7		77.0	
Ppts with other cancer	2410	(0.51%)	3185	(0.53%)
Accessory sinus	0	(0.00%)	1	(<0.01%)
Adrenal gland	1	(<0.01%)	4	(<0.01%)
Anus	9	(<0.01%)	14	(<0.01%)
Appendix	3	(<0.01%)	7	(<0.01%)
Biliary tract, parts of (other/unspecified)	31	(0.01%)	30	(<0.01%)
Bladder	135	(0.03%)	181	(0.03%)
Bones/joints/articular cartilage (limbs)	4	(<0.01%)	6	(<0.01%)
Bones/joints/articular cartilage (other)	4	(<0.01%)	2	(<0.01%)
Brain	63	(0.01%)	71	(0.01%)
Cervix	44	(0.01%)	36	(0.01%)
Central Nervous System (excludes brain)	0	(0.00%)	3	(<0.01%)
Connective/subcutaneous/soft tissues	21	(<0.01%)	35	(0.01%)
Endocrine glands, related structures	5	(<0.01%)	5	(<0.01%)
Esophagus	26	(0.01%)	29	(<0.01%)
Eye and adnexa	15	(<0.01%)	11	(<0.01%)
Genital organs	29	(0.01%)	17	(<0.01%)
Kidney	108	(0.02%)	140	(0.02%)
Larynx	11	(<0.01%)	10	(<0.01%)
Leukemia	107	(0.02%)	146	(0.02%)
Liver	26	(0.01%)	31	(0.01%)
Lung	479	(0.10%)	589	(0.10%)
Lymph nodes	11	(<0.01%)	9	(<0.01%)
Lymphoma,Hodgkins	14	(<0.01%)	14	(<0.01%)
Lymphoma,Non-Hodgkins	207	(0.04%)	301	(0.05%)
Melanoma of the skin	334	(0.07%)	422	(0.07%)
Multiple myeloma	86	(0.02%)	75	(0.01%)
Oral (mouth)	19	(<0.01%)	13	(<0.01%)
Palate	3	(<0.01%)	6	(<0.01%)
Pancreas	123	(0.03%)	148	(0.02%)
Parotid gland (Stensen's duct)	9	(<0.01%)	15	(<0.01%)
Peripheral nerves and autonomic nervous system	1	(<0.01%)	5	(<0.01%)
Pyriform sinus	0	(0.00%)	4	(<0.01%)
Respiratory system, intrathoracic, other	11	(<0.01%)	13	(<0.01%)
Salivary glands, major (other/unspecified)	2	(<0.01%)	10	(<0.01%)
Stomach	36	(0.01%)	36	(0.01%)
Thyroid	73	(0.02%)	81	(0.01%)
Tongue, part of (other/unspecified)	18	(<0.01%)	17	(<0.01%)
Urinary organs (other/unspecified)	8	(<0.01%)	19	(<0.01%)
Uterus, not otherwise specified	34	(0.01%)	63	(0.01%)
Other/unknown site of cancer	192	(0.04%)	236	(0.04%)
Other/unknown cancers reported on death form	179	(0.04%)	393	(0.07%)

Table 6.14
Locally Verified Other Fractures (Annualized Percentages): CT and OS Participants

Data as of: February 29, 2004

	CT		OS[1]	
Locally Verified				
Number of participants	68132		6365	
Mean follow-up time (months)	83.7		85.2	
Ppts with other fractures[2]	6528	(1.37%)	602	(1.33%)
Ankle	1166	(0.25%)	108	(0.24%)
Carpal bone(s) in wrist	161	(0.03%)	10	(0.02%)
Clavicle or collar bone	119	(0.03%)	13	(0.03%)
Elbow, not otherwise specified	22	(<0.01%)	1	(<0.01%)
Humerus, shaft/unspecified	71	(0.01%)	6	(0.01%)
Humerus, upper end	712	(0.15%)	55	(0.12%)
Humerus, lower end	79	(0.02%)	7	(0.02%)
Metacarpal bone(s)	227	(0.05%)	20	(0.04%)
Patella	292	(0.06%)	27	(0.06%)
Pelvis	268	(0.06%)	42	(0.09%)
Radius or ulna	1843	(0.39%)	182	(0.40%)
Sacrum and coccyx	80	(0.02%)	10	(0.02%)
Scapula	31	(0.01%)	6	(0.01%)
Shaft of femur	92	(0.02%)	8	(0.02%)
Tarsal/metatarsal bones	1099	(0.23%)	113	(0.25%)
Tibia and fibula	552	(0.12%)	30	(0.07%)
Tibial plateau	141	(0.03%)	10	(0.02%)
Upper radius/ulna	330	(0.07%)	31	(0.07%)
Unknown other fracture	4	(<0.01%)	0	(0.00%)
Self-Reports				
Number of participants			93676	
Mean follow-up time (months)			77.0	
Elbow			560	(0.09%)
Foot			1966	(0.33%)
Hand			372	(0.06%)
Knee			644	(0.11%)
Lower Arm			2821	(0.47%)
Lower Leg			2223	(0.37%)
Pelvis			537	(0.09%)
Tailbone			156	(0.03%)
Upper Arm			1166	(0.19%)
Upper Leg			311	(0.05%)
Vertebra			1308	(0.22%)
Other Fracture			2262	(0.38%)

[1] Locally verified other fractures for OS Participants are only confirmed in the three bone density clinics.
[2] "Other fractures" excludes fractures indicated as pathological.

Table 6.15
Cause of Death (Annualized Percentages): CT and OS Participants

Data as of: February 29, 2004

	CT		OS	
Number Randomized	68132		93676	
Mean Follow-up Time (months)	83.7		77.0	
Total death	2824	(0.59%)	4392	(0.73%)
Adjudicated death	2692	(0.57%)	4205	(0.70%)
Centrally adjudicated death	2285	(0.48%)	0	(0.00%)
Locally adjudicated death (final)	195	(0.04%)	3860	(0.64%)
Temporary adjudicated death	206	(0.04%)	326	(0.05%)
Identified by NDI search	6	(<0.01%)	16	(<0.01%)
Cardiovascular				
Atherosclerotic cardiac	450	(0.09%)	524	(0.09%)
CHD deaths locally adjudicated before 10/99	N/A	N/A	82	(0.01%)
Definite CHD deaths	224	(0.05%)	210	(0.03%)
Possible CHD deaths	226	(0.05%)	232	(0.04%)
Cerebrovascular	202	(0.04%)	329	(0.05%)
Pulmonary embolism	31	(0.01%)	32	(0.01%)
Other cardiovascular	127	(0.03%)	246	(0.04%)
Unknown cardiovascular	14	(<0.01%)	65	(0.01%)
Total cardiovascular deaths	824	(0.17%)	1196	(0.20%)
Cancer				
Breast cancer	66	(0.01%)	271	(0.05%)
Ovarian cancer	88	(0.02%)	132	(0.02%)
Endometrial cancer	13	(<0.01%)	35	(0.01%)
Colorectal cancer	124	(0.03%)	155	(0.03%)
Other cancer	892	(0.19%)	1210	(0.20%)
Unknown cancer site	63	(0.01%)	102	(0.02%)
Total cancer deaths	1246	(0.26%)	1905	(0.32%)
Accident/injury				
Homicide	6	(<0.01%)	7	(<0.01%)
Accident	69	(0.01%)	85	(0.01%)
Suicide	13	(<0.01%)	20	(<0.01%)
Other injury	5	(<0.01%)	8	(<0.01%)
Total accidental deaths	93	(0.02%)	120	(0.02%)
Other				
Other known cause	396	(0.08%)	702	(0.12%)
Unknown cause	133	(0.03%)	282	(0.05%)
Total deaths – other causes	529	(0.11%)	984	(0.16%)

Table 6.16
Results of NDI Search[1]

	Known dead[2]		Lost to follow-up[3]		Known alive[4]	
	N	%	N	%	N	%
Submitted to NDI	1252		2249		500	
NDI returned matches	1235	98.6	731	32.5	149	29.8
Matches satisfying WHI criteria	1224	97.8	53	2.4	0	0.0
Reported dead to WHI after 8/31/2000	N/A		29	1.3[5]	N/A	
Reported alive to WHI after 8/31/2000[6]	N/A		2	<1.0[7]	N/A	
Only identified using NDI	N/A		22	1.0[8]	N/A	

[1] Analysis has not been updated from that of August 31, 2001.
[2] Participants having a Form 120 or Form 124 with date of death before 1/1/2000.
[3] Participants who were lost-to-follow-up or no-follow-up by 8/31/2000, for whom contact was before 1/1/2000.
[4] Randomly selected participants with whom there was clinic contact after 1/1/2000.
[5] 2 of these participants were CT participants, 27 were OS participants.
[6] Not counted as dead in this report or DSMB report.
[7] 1 of these participants was a CT participant, 1 was an OS participant.
[8] 6 of these participants were CT participants, 16 were OS participants.

Table 6.17
Lost-to-Follow-up and Vital Status by Clinic: CT Participants

Data as of: February 29, 2004

	Deceased		Alive: Current Participation[1]		Alive: Recent Participation[2]		Alive: Past/Unknown Participation[3]		Stopped Follow-up[4]		Lost to Follow-up[5]		Total
	N	%	N	%	N	%	N	%	N	%	N	%	N
Clinic													
Atlanta	77	4.5	1594	92.6	7	0.4	2	0.1	23	1.3	18	1.0	1721
Birmingham	92	5.0	1665	90.9	24	1.3	0	0.0	30	1.6	21	1.1	1832
Bowman	70	4.6	1348	87.9	19	1.2	0	0.0	55	3.6	41	2.7	1533
Brigham	82	3.6	2180	94.8	12	0.5	5	0.2	19	0.8	2	0.1	2300
Buffalo	74	4.6	1490	93.2	5	0.3	0	0.0	27	1.7	2	0.1	1598
Chapel Hill	60	3.9	1439	93.6	2	0.1	0	0.0	30	2.0	7	0.5	1538
Chicago	75	4.6	1454	89.5	23	1.4	0	0.0	51	3.1	22	1.4	1625
Chi-Rush	57	4.3	1172	88.6	21	1.6	1	0.1	34	2.6	38	2.9	1323
Cincinnati	42	3.0	1296	93.2	0	0.0	0	0.0	50	3.6	2	0.1	1390
Columbus	63	4.1	1430	92.3	11	0.7	0	0.0	33	2.1	13	0.8	1550
Detroit	34	2.5	1183	85.8	28	2.0	2	0.1	112	8.1	19	1.4	1378
GWU-DC	52	3.4	1409	92.8	35	2.3	1	0.1	16	1.1	5	0.3	1518
Gainesville	87	4.2	1911	91.7	15	0.7	1	<0.1	57	2.7	13	0.6	2084
Honolulu	51	3.6	1225	87.1	44	3.1	5	0.4	62	4.4	19	1.4	1406
Houston	39	3.1	1073	84.2	81	6.4	1	0.1	59	4.6	21	1.6	1274
Iowa City	104	4.3	2271	93.3	8	0.3	0	0.0	29	1.2	22	0.9	2434
Irvine	50	3.1	1465	90.3	17	1.0	1	0.1	55	3.4	34	2.1	1622
L.A.	66	3.9	1532	91.4	10	0.6	0	0.0	52	3.1	17	1.0	1677
La Jolla	106	4.9	1837	84.9	65	3.0	1	<0.1	44	2.0	111	5.1	2164
Madison	39	2.5	1482	95.2	11	0.7	1	0.1	23	1.5	1	0.1	1557
Medlantic	71	4.8	1326	89.2	17	1.1	1	0.1	45	3.0	27	1.8	1487
Memphis	98	5.6	1554	89.4	2	0.1	0	0.0	71	4.1	13	0.7	1738
Miami	47	3.2	1228	82.7	32	2.2	0	0.0	57	3.8	121	8.1	1485
Milwaukee	60	3.6	1524	92.5	2	0.1	0	0.0	53	3.2	9	0.5	1648
Minneapolis	83	4.2	1844	92.8	34	1.7	0	0.0	26	1.3	1	0.1	1988
NY-City	75	4.0	1669	88.7	73	3.9	7	0.4	31	1.6	27	1.4	1882
Nevada	80	5.4	1364	92.4	7	0.5	0	0.0	19	1.3	6	0.4	1476
Newark	89	3.6	2182	89.3	61	2.5	3	0.1	86	3.5	22	0.9	2443
Oakland	61	3.9	1464	94.0	4	0.3	0	0.0	19	1.2	9	0.6	1557
Pawtucket	105	4.0	2447	92.4	8	0.3	0	0.0	69	2.6	18	0.7	2647
Pittsburgh	82	4.9	1534	92.6	8	0.5	0	0.0	32	1.9	1	0.1	1657
Portland	74	4.5	1463	89.3	31	1.9	1	0.1	38	2.3	31	1.9	1638
San Antonio	36	2.6	1229	88.5	7	0.5	1	0.1	90	6.5	26	1.9	1389
Seattle	84	4.6	1613	89.2	35	1.9	3	0.2	45	2.5	29	1.6	1809
Stanford	63	3.6	1611	92.2	13	0.7	0	0.0	45	2.6	16	0.9	1748
Stonybrook	57	4.2	1250	92.3	18	1.3	0	0.0	26	1.9	3	0.2	1354
Torrance	37	3.7	869	86.9	23	2.3	0	0.0	44	4.4	27	2.7	1000
Tucson	125	6.0	1808	86.2	17	0.8	0	0.0	45	2.1	103	4.9	2098
U.C. Davis	113	5.8	1706	88.2	43	2.2	0	0.0	47	2.4	26	1.3	1935
Worcester	64	3.9	1529	93.9	18	1.1	0	0.0	7	0.4	11	0.7	1629
Total	2824	4.1	61670	90.5	891	1.3	37	0.1	1756	2.6	954	1.4	68132

[1] Participants who have filled in a Form 33 within the last 9 months.
[2] Participants who last filled in a Form 33 between 9 and 18 months ago.
[3] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 6.18
Lost-to-Follow-up and Vital Status by Clinic: OS Participants

Data as of: February 29, 2004

	Deceased		Alive: Current Participation[1]		Alive: Recent Participation[2]		Alive: Past/Unknown Participation[3]		Stopped Follow-up[4]		Lost to Follow-up[5]		Total
	N	%	N	%	N	%	N	%	N	%	N	%	N
Clinic													
Atlanta	107	4.3	2311	93.8	19	0.8	0	0.0	10	0.4	16	0.6	2463
Birmingham	140	5.5	2176	86.0	108	4.3	0	0.0	60	2.4	45	1.8	2529
Bowman	94	4.2	1996	89.6	57	2.6	0	0.0	39	1.8	41	1.8	2227
Brigham	80	2.7	2755	93.5	77	2.6	7	0.2	16	0.5	11	0.4	2946
Buffalo	155	6.9	2039	90.7	25	1.1	1	<0.1	22	1.0	6	0.3	2248
Chapel Hill	76	3.6	1971	94.6	12	0.6	0	0.0	19	0.9	5	0.2	2083
Chicago	88	4.7	1677	88.8	45	2.4	2	0.1	32	1.7	45	2.4	1889
Chi-Rush	105	5.1	1746	85.2	68	3.3	10	0.5	43	2.1	77	3.8	2049
Cincinnati	98	4.4	1976	87.9	69	3.1	7	0.3	49	2.2	50	2.2	2249
Columbus	85	3.8	2057	92.7	50	2.3	3	0.1	17	0.8	7	0.3	2219
Detroit	76	3.6	1849	87.5	54	2.6	0	0.0	95	4.5	38	1.8	2112
GWU-DC	99	4.4	2104	93.6	28	1.2	4	0.2	8	0.4	4	0.2	2247
Gainesville	130	4.7	2545	91.2	20	0.7	3	0.1	72	2.6	22	0.8	2792
Honolulu	71	3.4	1801	85.2	62	2.9	15	0.7	104	4.9	60	2.8	2113
Houston	127	6.0	1879	88.2	24	1.1	1	<0.1	75	3.5	24	1.1	2130
Iowa City	120	3.8	2915	93.4	14	0.4	0	0.0	46	1.5	25	0.8	3120
Irvine	94	4.2	2011	90.2	24	1.1	0	0.0	55	2.5	46	2.1	2230
L.A.	89	4.1	2030	92.5	25	1.1	0	0.0	36	1.6	15	0.7	2195
La Jolla	199	5.7	2939	84.9	132	3.8	5	0.1	30	0.9	158	4.6	3463
Madison	95	4.8	1847	93.2	19	1.0	0	0.0	20	1.0	0	0.0	1981
Medlantic	104	4.7	2005	91.4	16	0.7	1	<0.1	35	1.6	32	1.5	2193
Memphis	133	5.3	2230	88.6	36	1.4	6	0.2	105	4.2	6	0.2	2516
Miami	62	4.5	1017	74.0	94	6.8	1	0.1	36	2.6	164	11.9	1374
Milwaukee	86	3.8	2034	90.6	31	1.4	2	0.1	39	1.7	54	2.4	2246
Minneapolis	92	3.4	2490	91.3	62	2.3	2	0.1	36	1.3	45	1.7	2727
NY-City	144	5.0	2474	85.2	129	4.4	22	0.8	25	0.9	109	3.8	2903
Nevada	168	7.7	1974	90.8	9	0.4	0	0.0	20	0.9	3	0.1	2174
Newark	119	3.5	2964	87.9	145	4.3	4	0.1	78	2.3	63	1.9	3373
Oakland	117	5.7	1868	91.0	30	1.5	0	0.0	25	1.2	13	0.6	2053
Pawtucket	151	4.2	3214	89.6	59	1.6	85	2.4	59	1.6	20	0.6	3588
Pittsburgh	111	5.8	1660	86.6	47	2.5	0	0.0	59	3.1	40	2.1	1917
Portland	98	4.4	2046	91.7	21	0.9	0	0.0	39	1.7	28	1.3	2232
San Antonio	76	3.9	1642	84.6	91	4.7	1	0.1	103	5.3	29	1.5	1942
Seattle	109	6.6	1433	86.2	51	3.1	14	0.8	28	1.7	28	1.7	1663
Stanford	127	4.8	2433	91.2	43	1.6	4	0.1	50	1.9	12	0.4	2669
Stonybrook	79	3.9	1895	93.4	31	1.5	0	0.0	14	0.7	9	0.4	2028
Torrance	73	4.9	1318	87.7	27	1.8	3	0.2	40	2.7	42	2.8	1503
Tucson	190	6.8	2404	86.4	11	0.4	3	0.1	84	3.0	90	3.2	2782
U.C. Davis	130	5.7	2041	90.0	40	1.8	4	0.2	36	1.6	18	0.8	2269
Worcester	95	4.2	2096	93.6	28	1.3	1	<0.1	14	0.6	5	0.2	2239
Total	4392	4.7	83862	89.5	1933	2.1	211	0.2	1773	1.9	1505	1.6	93676

[1] Participants who have filled in a Form 33 within the last 15 months.
[2] Participants who last filled in a Form 33 between 15 and 24 months ago.
[3] Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

7. Laboratory Studies

7.1 Overview

Blood samples are collected on all CT participants at baseline and year 1 and on a 6% subsample of participants at years 3, 6, and 9. Blood samples are collected on all OS participants at baseline and Year 3. All blood samples are obtained in the fasting state (at least 12 hours), maintained at 4°C for up to one hour until plasma or serum is separated from cells. In addition, urine samples are collected on both CT and OS participants at the three Bone Density Clinical Centers at baseline, year 1 and year 9 for CT, and baseline and year 3 for OS participants. Barcoded plasma, serum, RBCs, buffy coat, and urine aliquots are frozen at -70°C and sent on dry ice to the central repository (McKesson Biological Services, Rockville, MD) where storage at -70°C is maintained.

7.2 Status of Analyses

Core Analytes

The analyses of the twenty core analytes are done by Medical Research Laboratories, Highland Heights, Kentucky (MRL). MRL has completed the analyses of the CT 6% subsample core analytes for baseline, year 1, and year 3 samples. Analysis of year 6 bloods began in September 2002 and is ongoing with about 500 samples analyzed every three months. Analysis of year 6 bloods is expected to start in early 2005. See *Table 7.1* for a list of the assays included in the core analytes. See *Sections 2* and *3* in this report for presentation of the laboratory results for HT and DM.

MRL completed the analysis of the 1% OS Measurement Precision Study (OS-MPS). See *Section 5.3* in the February 1, 1999 to August 25, 1999 Semi-Annual Progress Report for the results.

DNA Extraction

Up through the end of 2003, DNA extraction for WHI was done by BioServe Biotechnologies, Laurel, MD. For each buffy coat sample, BioServe prepared up to four daughter aliquots containing 3 µg DNA each and divided the remaining DNA into parent aliquots containing up to 150 µg DNA each, depending on the quantity of DNA extracted. During 2003, the Laboratory Working Group noted that the average DNA yield from buffy coat extractions dropped from about 24 µg per 1,000 WBC to 13-17 µg DNA. The Working Group put a hold on further buffy coat extractions, discussed possible causes for this decrease in yield, and had several comparison extraction runs done using different extraction procedures. Review of the results of the comparison runs is expected to be completed in early March 2004, followed by resumption of extractions.

In September 2003 the Executive Committee approved a reduction in the standard amount of DNA available in the daughter aliquots from 3 µg to 1 µg. This change was made due to advancements in technology which have made it possible to use smaller amounts of DNA for genetic studies and a continuing commitment to conserve the precious resource of WHI biologic samples. The concentration of DNA remains the same at 50 ng/µl, with the daughter aliquots containing 20 µl rather than 60 µl sample. Ancillary studies approved before October 2003 for 3 µg DNA were asked if they require the full 3 µg DNA or if they can reduce the sample to 1 µg

and four ASs agreed to a reduction. Those studies requiring 3 µg DNA will receive the requested amount.

To date, BioServe has completed the DNA extraction of over 5,400 samples, including samples for the CVD Biomarker Case Control Study of CHD, Stroke, and VTE in the HT Clinical Trial, for AS #83 (Paul Ridker, coronary heart disease), and AS # 108 (Henry Lin, colorectal cancer). Extraction for AS #132 (Simon Liu, Type 2 Diabetes Mellitus) began in January 2003 and is ongoing. Extraction for AS #146 (Charles Fuchs, pancreatic cancer) and AS #150 (Gloria Ho, breast, colorectal, and endometrial cancers) is planed for early spring. Through the end of 2005, an average of 500 samples will be extracted per month.

CVD Biomarker Case-Control Study of CHD, Stroke, and VTE in the HT Clinical Trial
This study is divided into two phases, with phase I including all locally adjudicated cases of CHD, stroke, and VTE occurring within two years of randomization and phase II including similar types of cases occurring more than two years after randomization. The University of Leiden was contracted to perform the initial DNA testing for the study, MRL to perform the lipid analyses, and the University of Vermont to perform the thrombosis assays. Results from these assays have been received.

In mid-2003, glucose and insulin were added and in the fall the Steering Committee approved adding eight additional polymorphisms. In February 2005, the Steering Committee also approved several additional assays, including 10 lipoprotein subfractions, LDL particle size and concentration, MMP-7, MMP-8, a panel of 10 cytokines, APC-ETP, free and total TFPI, and progesterone polymorphisms. The CCC will issue RFPs for laboratories to perform these assays in early Spring. *Table 7.1* lists all the assays for this study and *Table 7.2* shows the number completed and expected assays for the Estrogen-plus-Progestin and the E-alone cases and controls. PIs can arrange to see the E-Alone data on the WHI website.

Genome-wide Scan of Single Nucleotide Polymorphisms (SNPs) in Relation to Coronary Heart Disease, Stroke, and Breast Cancer
Following the Fall 2003 SC meeting the CCA-WG developed a proposal for a study of E+P and E-alone effects in relation to genome-wide SNPs for CHD, breast cancer, and stroke. This proposal was approved by SC in April 2004, subject to supportive external review. An RFP has been drafted and plans are being made to obtain additional external review, toward potential implementation in mid- to late-2004.

Proteomic Patterns in Relation to Colorectal Cancer in the Hormone Therapy Trials and Observational Study.
The CCA-WG has also followed up on the Fall 2003 SC discussion of proteomic analyses in the HT trials. Since the colorectal cancer data in relation to E+P and E-alone are in need of biological elucidation a concept has been drafted toward identifying peptide peaks that may distinguish colorectal cancer cases and controls, and that may distinguish E+P and E-alone users from non-users. Following discussion with potential collaborators at the National Cancer Institute, the concept is that colorectal cases and control plasma specimens from the OS would first be analyzed to identify peaks using Q-star technology, with specimens from the HT trial to be considered at a later stage for validation purposes.

Hormones

Esoterix (Calabasas Hills, CA; formerly Endocrine Sciences) has completed hormone analyses on baseline and year 1 samples for the 300 participants included in the approved paper "Correlates of endogenous sex hormone concentrations in WHI". (See *Table 7.1* for a list of the analytes.) Final results were received in March 2003 and analyses of the data are near completion.

In mid-2003 the Laboratory Working Group recommended that the CCC identify a hormone laboratory with an estradiol assay that uses 0.5 ml or less sample. An RFP was issued in August 2004 and the Laboratory Working Group selected Frank Stanczyk, Director, Reproductive Endocrine Research Laboratory, USC Keck School of Medicine, Women's & Children's Hospital, Los Angeles, California, to perform future WHI hormone assays for WHI.

Ancillary Studies

Currently, WHI has made available 1.8 ml baseline and 1.8 ml Year 3 serum, citrate plasma, and EDTA plasma samples for use by OS ancillary studies. CT DNA samples are also likely to be made available for ancillary studies in late 2003. Eleven ancillary studies submitted proposals for the Spring 2005 OS blood competition, with one requesting CaD DNA samples. As of February 29, 2004, WHI has 25 currently approved ancillary studies using WHI blood specimens, with 17 funded, 2 submitted for funding, and 6 not yet submitted. Ancillary studies that do not obtain funding within 30 months of WHI approval are removed from the approval list and from the list of committed blood sample. *Table 7.3* gives a summary of the volume of OS blood samples committed to OS ancillary studies by disease type as of February 29, 2004. To date, no more baseline serum is available for current CHD and hip fracture cases, and very limited baseline citrate and EDTA plasma is available for stoke cases.

Analyses of blood samples for ancillary studies greatly increased over the last six months and are scheduled to increase further over the next year. Blood analyses for AS #105 (Julie Mares-Perlman, carotenoids in eye disease) began in December 2002, and is near completion. Sample selection and laboratory testing of specimens for AS #129 (Howard Strickler, colorectal, breast, and endometrial cancers) began in March and completion of blood analyses is expected before the end of the year. In the last six months processing of samples was also started for AS #97 (Garnet Anderson, ovarian cancer), AS #108 (Henry Lin, colorectal cancer), AS #121 (Francesmary Modugno, ovarian cancer), AS #132 (Simon Liu, Type 2 Diabetes Mellitus), and AS #134 (Francesmary Modugno, breast cancer). Selection of samples, processing, and testing for four additional ancillary studies are expected to being in the next six months. *Table 7.3* lists the approved ancillary studies by disease type and also lists the corresponding blood and DNA assays. *Table 9.2 – Ancillary Studies* lists additional key information about ancillary studies, including sample size and funding dates.

Table 7.1
Summary of WHI Blood Studies
By CT/OS and Disease Type

Disease[1]	WHI or AS #	Title	Study PI	Analyte
CT Studies				
-	**CT**	Core analytes (6% at baseline, Y1, Y3, Y6, Y9)	-	Alpha-carotene, beta-carotene, alpha-tocopherol, gama-tocopherol, beta-cryptoxanthine, lutein+zeaxanthin, lycopene, retinol, glucose, insulin, FVII Ag, FVIIc, fibrinogen, cholesterol, triglyceride, HDL, T17HDL-2, HDL-3, LDL, Lp(a)
-	**OS**	OS Measurement Precision Study (OS-MPS) (800 at baseline and 3 months)	-	Same as core analytes
-	**DM**	DM Hormone (300 at baseline and Y1)	-	Albumin, androstenedione, bioavailable estradiol, DHEA, DHES, DHT, estradiol, estrone, estrone-sulfate, progesterone, prolactin, SHBG, testosterone
-	**CaD**	Vitamin D (460 at Y3)	-	25-hydroxy vitamin D_3
CHD, Stroke, VTE	**HT**	CVD Biomarker Study (400 CHD, 270 stroke, 222 VTE baseline and Y1)	-	APC resistance, ATIII, CRP, D-dimer, E-selectin, PAI-1 Ag, protein C, protein S total, protein S free, F1+2, FVII Ag, FVIIIc, FIXc, FXIc, fibrinogen, PAP, MMP-9, TAFI, IL-1 beta, TFB1, TGF-beta, glucose, insulin, cholesterol, HDL, triglyceride, LDL, LDL particle size (12 measures), Lp(a), homocysteine, vWF. *Added in 2004:* 10 lipoprotein subfractions, MMP-7, MMP-8, TMP-1, 10 interleukins, APC-ETP, free TFPI, total TFPI, TFPI activity **DNA:** FXII val34leu, FV-HR2, FV-Leiden, MTHFR, PT19911, PT20210, PAI-1, MTHFR, ERα-PvuII4, ERα-1989/G, ER β-1730A/G, ER β-CArepeats, GPIβα-Kob,a, GPIβα-VNTR, GPIIIα-P1A1-A2, Integrin α2-807C/T *Added in 2004:* progesterone receptor polymorphisms
OS Ancillary Studies				
Cardiovascular				
CHD	**83**	Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study	Paul Ridker	tPA, PAI-1, honocysteine, D-dimer, C-RP, IL-6, sICAM-1, F1+2; **DNA:** Polymorphisms associated with the markers including Factor V Leiden
CHD	**110**	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Kathryn Rexrode	Free and total testosterone, Free and total estradiol, SHBG, DHES
CHD	**137**	Platelet Polymorphisms as Risk Factors for Myocardial Infarction in Postmenopausal Women and their Interactions with Hormone Replacement Therapy	Paul Bray	**DNA:** GPIIIa PI (A1),(A2), GPIbα thr/met145, GPIbα VNTR B/C, Integrin α2 807 T/C, ER β CA dinucleotide repeat, ER β 846 G→A, ER β 1082 G→A, ER β 1730 A→G
CHD	**164**	The IGF System and Coronary Heart Disease[2]	Robert Kaplan	Total IGF-I, IGFBP-3

Table 7.1
Summary of WHI Blood Studies
By CT/OS and Disease Type

Disease[1]	WHI or AS #	Title	Study PI	Analyte
CHD	**165**	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke	Katherine Hartmann	TSH, Free T4, TPO Ab
Stroke	**126**	Hormones and Biomarkers Predicting Stroke in Women	Sylvia Wassertheil-Smoller	CRP, IL-6, TNF alpha, VCAM-1, E-selectin, MMP-9, F1+2, PAI-1, t-PA, PAP, D-dimer, APC resistance, vWF, FVII antigen, FVII activity, fibrinogen, TC, triglycerides, HDL , Lp(a), glucose, insulin, homocysteine
Stroke	**165**	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke	Katherine Hartmann	TSH, Free T4, TPO Ab
Stroke	**169**	Risk Factors for Hemorrhagic Stroke Among Postmenopausal Women[2]	Robert Kaplan	Total cholesterol, HDL, LDL. Triglyceride, insulin, glucose, MMP-2, MMP-9, elastase, hs-CRP **DNA**: ApoE genotype (ε2, ε3, ε4)
Hypertension	**133**	Biochemical and Genetic Markers of Hypertension in White and Black Women	Howard Sesso	CRP, sICAM-1, IL-6, TNF-α, and IL-1β, AGT, ACE. **DNA**:, AT1R, α-adducin genes
Fracture				
Hip fracture	**90[3]**	Biochemical and Genetic Determinants of fracture in postmenopausal women	Steve Cummings	ESR1, Total and bioavailable estradiol, IGF-1, LRP5, SHBG **DNA**: VDR FOKI, Coll A1 Sp1, ApoE4, TGF-beta-1(Leu10pro)
Hip fracture	**181[3]**	Estradiol, cytokines and bone turnover: Effects on hip fracture[2]	Jane Cauley	TNFalphaSR1, TNFalphaSR-2, IL-6sR, OPG, RANKL, PINP, CTx
Cancer				
Breast Cancer	**129[4]**	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Howard Strickler	Glucose, insulin, IGF-1, IGF free, IGFBP-3, estradiol
Breast Cancer	**134**	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Francesmary Modugno	2-OH estrone, 16a-OH estrone
Breast Cancer	**149**	Molecular Epidemiology and Prevention of Breast Cancer	Jennifer Hu	Fatty acid profile, lipid peroxidation. **DNA**: oxidative DNA damage, GSTM1/P1/T1 genotypes, DNA repair genes

Table 7.1
Summary of WHI Blood Studies
By CT/OS and Disease Type

Disease[1]	WHI or AS #	Title	Study PI	Analyte
Breast Cancer	**152**[4]	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Gloria Ho	**DNA**: genes for IGF-1, IGF BP-3, insulin, insulin receptor substrate 1
Breast Cancer	**155**	Carotenoids, Transforming Growth Factors, and Breast Cancer Risk[2]	Tom Rohan	Alpha-carotene, beta-carotene, cryptoxanthin, lutein, lyocopene+zeaxanthin, retinol,TGFB-1. **DNA**: polymorphisms of TGFB-1, TGFB receptor type I,II,III
Breast Cancer	**167**	Sex Hormones, Risk Factors, and Risk of ER+ and ER- Breast Cancer[2]	Steve Cummings	SHBG, total estradiol, total testosterone
Colorectal Cancer	**108.1**	Gene-environment effects and colorectal cancer	Henry Lin	**DNA:** GSTM1 and GSTT1 null genotypes; PTGS2/Cox-2 Val511Ala mutation
Colorectal Cancer	**129**[4]	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Howard Strickler	Glucose, insulin, IGF-1, IGFBP-3, estradiol
Colorectal Cancer	**152**[4]	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Gloria Ho	**DNA**: genes for IGF-1, IGF BP-3, insulin, insulin receptor substrate 1
Endometrial Cancer	**129**[4]	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Howard Strickler	Glucose, insulin, IGF-1, IGFBP-3, estradiol
Endometrial Cancer	**152**[4]	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Gloria Ho	**DNA**: genes for IGF-1, IGF BP-3, insulin, insulin receptor substrate 1
Leukemia	**148**	Relationship Between Monoclonal Hemopoiesis and other Molecular Abnormalities and the Development of Leukemia in Older Women[2]	Harvey Preisler	**DNA:** Clonality of hemoporesis, N-ras mutation, methylation of p15 gene
Ovarian Cancer	**97**	Modeling serum markers for cost-effective ovarian cancer screening	Garnet Anderson	CA-125, M-CSF, OVX1
Ovarian Cancer	**121**	Hyperinsulinemia and Ovarian Cancer	Francesmary Modugno	Insulin, glucose, IGF-I, IGFBP-I, IGFBP-3
Pancreatic Cancer	**146**	A Prospective Study of Pancreatic Cancer Pathogenesis	Charles Fuchs	B12, C-peptide, CYP1A1, folate, GST, homocysteine, IGF-I, IGF-II, IGFBP-1, IGFBP-3, insulin. **DNA:** NAT1, NAT2, MTHFR, PLP

Table 7.1
Summary of WHI Blood Studies
By CT/OS and Disease Type

Disease[1]	WHI or AS #	Title	Study PI	Analyte
Other				
Diabetes Mellitus, Type II	**132**	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Simin Liu	TNF-R2, IL-6, CRP, ICAM-1, VCAM-1, E-selectin, insulin, glucose. **DNA:** PPAR-g2Pro12AIa, TNF alpha G308A, E-selectin ser128Arg, UCP2, CAPN10, AP2, NOS3
Diabetes	**180**	Macrovascular Complications of Diabetes in Postmenopausal Women[2]	Rongling Li	DNA: AGT, AGTR1, ACE, NOS3, GNB3, ADRB2, PPARG, RETN, TNF and UCP3
Eye disease	**105**	Carotenoids in Age-Related Eye Disease Study	Julie Mares-Perlman	Alpha-carotene, beta-carotene, 9-cis-beta-carotene,13-cis-beta-carotene, alpha-tocopherol, cryptoxanthine, gama-tocopherol, lutein, lycopene, cis-lycopene, retinol, retinyl palmitatem, zeaxanthin, cholesterol, triglyceride
Frailty/ Disability	**179**	Inflammation and Coagulation Pathways in the Etiology of Frailty and Disability in Older Women[2]	Andrea LaCroix	CRP, fibrinogen, F-VII, F-VIII, PAP complex, D-dimer, Factor XI alpha 1-antitrypsin,IL-6. **DNA:** ACE gene insertion (I) polymorphism, two promotor polymorphisms (-174G/C and -572G/C) of IL-6 gene

[1] Some ancillary studies include more than one disease.

[2] Pending funding.

[3] Ancillary studies 90 and 181 share cases and controls.

[4] Ancillary studies 129 and 152 share cases and controls.

Table 7.2
Number of Assays Completed in CVD Biomarker Study:
Estrogen-plus-Progesterone Cases and Controls
Cases as of February 2001

	CHD				Stroke				VTE					
	Cases		Controls		Cases		Controls		Cases		Controls		All Controls[2]	
Assays[1]	Baseline (N=229)	Year 1 (N=156)	Baseline (N=229)	Year 1 (N=162)	Baseline (N-145)	Year 1 (N=104)	Baseline	Year 1 (N=112)	Baseline (N=152)	Year 1 (N=87)	Baseline (N=152)	Year 1 (N=96)	Baseline (N-512)	Year 1 (N=359)
Inflamation														
CRP	222	148	216	151	140	97	142	110	149	85	149	91	494	341
E-selectin	218	150	222	153	141	99	144	108	-	-	147	90	500	341
IL6	220	148	224	154	140	96	143	109	-	-	146	90	500	342
Ils (10)[3]	*	-	*	-	*	-	*	-	-	-	-	-	-	-
MMP-9	229	154	228	156	145	103	145	111	-	-	152	92	512	349
MMP-7[3]	*	*	*	*	*	*	*	*	-	-	-	-	-	-
MMP-8[3]	*	*	*	*	*	*	*	*	-	-	-	-	-	-
TFPI, free[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
TFPI, total[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
TFPI activity[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
TMP-1[3]	*	*	*	*	*	*	*	*	-	-	-	-	-	-
Thrombosis														
Antithrombin III	-	-	222	149	-	-	140	104	149	85	148	86	497	335
D-dimer	226	153	227	155	142	101	145	110	150	86	152	90	511	344
Factor VIII	226	153	228	155	142	101	144	110	151	86	152	91	511	345
Factor IX Conc	-	-	226	-	-	-	144	-	150	-	151	-	508	-
Fibrinogen	226	153	228	155	142	101	144	110	151	86	152	91	511	345
Fragment 1+2	209	141	208	149	132	93	140	106	142	82	141	90	477	334
PAI-1	211	143	210	150	132	94	142	109	143	83	143	91	483	339
PAP	211	143	209	150	132	94	142	108	143	83	143	91	482	338
Protein C	-	-	160	-	-	-	109	-	105	-	112	-	371	-
Protein S Total	-	-	160	-	-	-	108	-	105	-	112	-	370	-
Protein S Free	-	-	160	-	-	-	108	-	104	-	110	-	368	-
Prothrombin Ag	-	-	219	150	-	-	142	106	147	84	148	88	496	340
TAFI	223	151	220	151	140	99	142	110	149	85	150	91	499	341
vWF	226	153	228	155	141	101	144	109	150	86	151	89	510	342
APC-ETP[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Other Analytes														
Homocysteine	228	153	228	155	143	101	145	109	152	86	151	92	511	345
Glucose[4]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Insulin[4]	*	*	*	*	*	*	*	*	*	*	*	*	*	*

Table 7.2
Number of Assays Completed in CVD Biomarker Study:
Estrogen-plus-Progesterone Cases and Controls
Cases as of February 2001

Assays[1]	CHD				Stroke				VTE				All Controls[2]	
	Cases		Controls		Cases		Controls		Cases		Controls			
	Baseline (N=229)	Year 1 (N=156)	Baseline (N=229)	Year 1 (N=162)	Baseline (N-145)	Year 1 (N=104)	Baseline	Year 1 (N=112)	Baseline (N=152)	Year 1 (N=87)	Baseline (N=152)	Year 1 (N=96)	Baseline (N-512)	Year 1 (N=359)
Lipids														
HDL Conc	218	144	219	148	141	100	141	102	142	77	144	88	492	329
HDL-2	215	142	218	148	140	99	140	102	141	77	144	87	490	328
HDL-3	215	142	218	148	140	99	140	102	141	77	144	87	490	328
LDL Conc	209	138	216	146	137	98	139	99	140	75	140	87	484	323
LDL Particle Size[5]	221	144	219	150	139	98	139	107	-	-	145	87	490	334
Lp(a)	207	133	211	143	137	98	136	101	-	-	131	84	466	320
Total cholesterol	220	144	220	148	141	101	141	102	142	77	144	88	493	329
Triglyceride	220	144	220	148	141	101	141	102	142	77	144	88	493	329
Lipoprotein subfractions (10)[3]	*	*	*	*	*	*	*	*	-	-	-	-	-	-
LDL particle conc[3]	*	*	*	*	*	*	*	*	-	-	-	-	-	-
Polymorphisms														
MTHF	227		228		144		143		146		149		507	
PAI-1	227		228		144		143		146		149		507	
Prothrombin 20210	227		228		144		143		146		149		507	
Prothrombin 19911	227		228		144		143		146		149		507	
Factor XIII val34leu	227		228		144		143		146		149		507	
ER α - PvuII[4]	*		*		*		*		*		*		*	
ER α - 1989 T/G[4]	*		*		*		*		*		*		*	
ER β - 1730 A/G[4]	*		*		*		*		*		*		*	
ER β - CA repeats[4]	*		*		*		*		*		*		*	
GPIβα - Kob,a[4]	*		*		*		*		*		*		*	
GPIβα - VNTR[4]	*		*		*		*		*		*		*	
GPIIIα - P1(A1),(A2)[4]	*		*		*		*		*		*		*	
Integrin α2- 807 C/T[4]	*		*		*		*		*		*		*	
Progesterone receptors[3]	*		*		*		*		-		-		-	

[1] Some assays done only on CHD/stroke cases and others done only on VTE cases.
[2] Controls may be matched to more than one case, and cases may be controls for other diseases in table.
[3] Assays added in 2004, to be completed after labs selected.
[4] Assays added in summer of 2003, to be completed in 2004.
[5] Includes 12 sizes: LDL1-7, LHDL, VLDL, MidA, MidB, and MidC

Table 7.2
Number of Assays Completed in CVD Biomarker Study:
E-Alone Cases and Controls
Cases as of February 2001

	CHD				Stroke				VTE					
	Cases		Controls		Cases		Controls		Cases		Controls		All Controls[2]	
Assays[1]	Baseline (N=173)	Year 1 (N=116)	Baseline (N=173)	Year 1 (N=124)	Baseline (N=124)	Year 1 (N=74)	Baseline (N=127)	Year 1 (N=86)	Baseline (N=71)	Year 1 (N=49)	Baseline (N=71)	Year 1 (N=49)	Baseline (N=365)	Year 1 (N=254)
Inflamation														
CRP	168	112	167	121	127	80	126	84	68	47	67	49	354	249
E-selectin	165	113	170	120	123	81	126	83	-	-	69	49	359	247
IL6	171	114	169	122	124	82	125	84	-	-	66	48	354	249
MMP-9	173	116	173	123	126	84	127	86	-	-	71	49	365	253
TFPI, Free[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
TFPI, total[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
TFPI activity[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Thrombosis														
Antithrombin III	-	-	170	121	-	-	117	80	68	46	69	49	351	247
D-dimer	172	115	172	123	126	83	126	86	70	47	71	49	364	253
TGFB[4]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Factor VIII	173	115	173	123	127	83	126	86	71	47	71	49	364	253
Factor IX Conc	-	-	172	-	-	-	125	-	71	-	70	-	361	-
Fibrinogen	173	115	173	123	127	83	126	86	71	47	71	49	364	253
Fragment 1+2	158	107	156	118	122	76	119	81	62	45	62	45	331	239
PAI-1	158	107	157	119	121	76	120	81	64	45	62	45	333	240
PAP	158	107	157	119	121	76	120	81	64	45	62	45	333	240
Protein C	-	-	115	-	-	-	91	-	46	-	46	-	247	-
Protein S Total	-	-	115	-	-	-	90	-	46	-	46	-	246	-
Protein S Free	-	-	113	-	-	-	90	-	46	-	46	-	244	-
Prothrombin Ag	-	-	169	120	-	-	123	84	65	46	67	49	353	249
TAFI	165	111	168	121	123	81	125	85	67	47	68	49	355	250
vWF	172	115	171	123	126	83	126	86	70	47	71	49	363	253
APC-BTP[3]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Other Analytes														
Homocysteine	173	115	173	124	126	83	127	85	71	47	71	49	365	253
Glucose[4]	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Insulin[4]	*	*	*	*	*	*	*	*	*	*	*	*	*	*

Table 7.2
Number of Assays Completed in CVD Biomarker Study:
E-Alone Cases and Controls
Cases as of February 2001

	CHD				Stroke				VTE					
	Cases		Controls		Cases		Controls		Cases		Controls		All Controls[2]	
Assays[1]	Baseline (N=173)	Year 1 (N=116)	Baseline (N=173)	Year 1 (N=124)	Baseline (N=124)	Year 1 (N=74)	Baseline (N=127)	Year 1 (N=86)	Baseline (N=71)	Year 1 (N=49)	Baseline (N=71)	Year 1 (N=49)	Baseline (N=365)	Year 1 (N=254)
Lipids														
HDL Conc	165	109	169	118	121	79	119	79	60	39	62	43	345	236
HDL-2	164	108	167	114	121	78	119	79	59	39	62	43	343	232
HDL-3	165	108	167	115	121	78	119	79	59	39	62	43	343	233
LDL Conc	156	104	164	112	117	74	117	76	58	36	61	43	337	227
LDL Particle Size[5]	165	109	166	116	121	79	124	83	-	-	62	46	346	240
Lp(a)	157	103	162	112	118	74	116	76	-	-	57	41	330	225
Total cholesterol	167	109	169	118	122	79	120	79	61	39	62	43	346	236
Triglyceride	167	109	169	118	122	79	120	79	61	39	62	43	346	236
Polymorphisms														
Factor V Leiden	172		172		122		126		70		67		359	
Factor V-HR2	172		172		122		127		70		67		359	
MTHF	172		172		122		128		70		67		359	
PAI-1	172		172		122		129		70		67		359	
Prothrombin 20210	172		172		122		130		70		67		359	
Prothrombin 19911	172		172		122		131		70		67		359	
Factor XIII val34leu	172		172		128		132		70		67		359	
ER α - PvuII[4]	*		*		*		*		*		*		*	
ER α - 1989 T/G[4]	*		*		*		*		*		*		*	
ER β - 1730 A/G[4]	*		*		*		*		*		*		*	
ER β - CA repeats[4]	*		*		*		*		*		*		*	
GPIβα - Kob,a[4]	*		*		*		*		*		*		*	
GPIβα - VNTR[4]	*		*		*		*		*		*		*	
GPIIIα - P1(A1),(A2)[4]	*		*		*		*		*		*		*	
Integrin α2- 807 C/T[4]	*		*		*		*		*		*		*	

[1] Some assays done only on CHD/stroke cases and others done only on VTE cases.

[2] Controls may be matched to more than one case, and cases may be controls for other diseases in table.

[3] Assays added in 2004, to be completed after labs selected.

[4] Assays added in summer of 2003, to be completed in 2004.

[5] Includes 12 sizes: LDL1-7, LHDL, VLDL, MidA, MidB, and MidC

Table 7.3
OS Blood Committed to Ancillary Studies (AS)

				Volume Committed (Baseline/Year 3)			
Disease[1]	**Cases reported as of 2-04**	**AS #**	**Cases committed**	**Serum (ml)**	**Citrate Plasma (ml)**	**EDTA Plasma (ml)**	**DNA (µg)**
Cardiovascular							
CHD	1,818	83	650		1.0	0.5	3
		110	385	1.8[2]			
		137	1,060				3
		164[3]	350			0.3	
		165	800	0.25			
Stroke	1,528	126	1,100		1.5	1.5	
		165	750	0.25			
		169[3]	188	1.5			
Hypertension	18,312	133	800			0.8	2
Fracture							
Hip Fracture	784	90[4]	400	1.5			3
		181[4]	400	0.75[5]			
Cancer							
Breast Cancer	3,398	129[6]	900	0.25			
		134	200	0.3			
		149	800	0.2			1
		152[6]	900				3
		155[3]	3,500	0.3			1
		167[3]	400			1.0	
Colorectal Cancer	711	108	800				6
		129[6]	500	0.25			
		152[6]	500				3
Endometrial Cancer	464	129[6]	300	0.25			
		152[6]	300				3
Leukemia	146	148[3]	59				1
Ovarian Cancer	285	97	264 baseline, 132 Yr 3	1.0 baseline, 1.0 Yr 3			
		121	200	0.5			
Pancreatic Cancer	148	146	106			0.65	3
Other							
Diabetes	4,198	132	1,800			0.75	3
		180[3]	3,164				3
Eye Disease	See note 7	105	1,700	1.1			
Fragility/Disability	See note 7	179[3]	1,200		0.7	0.25	1

[1] Some ancillary studies include cases from more than one disease
[2] No more baseline sample available for selected cases
[3] Pending funding
[4] AS 90 and AS 181 share cases and controls
[5] D&A approved exceeding limit of 1.8 ml sample for this AS
[6] AS 129 and AS 152 share cases and controls

8. Clinical Center Performance Monitoring

8.1 Performance Monitoring

A four step plan is used to identify clinic-specific performance issues in a timely fashion, to reinforce good performance, and to provide assistance or institute corrective action if performance is inadequate. CCC staff train, monitor, and communicate with CC staff on an ongoing basis.

8.2 PMC Committee Activity

The Performance Monitoring Committee (PMC) provides a facilitating and monitoring role for CCs. In July 1998, the PMC separated its monitoring activities into two separate groups, with one group addressing outcomes and one group addressing adherence/retention and other issues. Membership of the Adherence and Retention PMC (A&R PMC) includes: Sally Shumaker, CFC PI, chair; Shari Ludlum and Linda Pottern, Project Office; Gerardo Heiss, Chapel Hill Clinical Center PI; Betty Caan, Oakland Clinical Center PI, Michelle Naughton, Steve Rapp, Sara Wilcox, CFC; and Barb Cochrane, Julie Hunt, Andrea LaCroix, Bernedine Lund, and Lesley Tinker, CCC. Membership of the Outcomes PMC (O-PMC) includes Anne McTiernan, CCC, chair; David Curb, Honolulu Clinical Center PI; Marian Limacher, Gainesville Clinical Center PI; Ronald Prineas, CFC; Jacques Rossouw and Shari Ludlum, Project Office; and Charles Kooperberg, Bernedine Lund, and Lori Proulx-Burns, CCC.

Both PMC subgroups discussed separately and together the option of recombining the two groups into one PMC. It was felt this consolidation was somewhat premature because of the monitoring the A&R PMC will do as the study moves through closeout. While the adherence part of the WHI is coming to an end, close-out activities need to be monitored up through September 2005, when CC operations other than outcomes will end. These activities will include CT and OS *Form 33 – Medical History Update* completion, CT close-out activities such as task completeness and unblinding completeness, CT and OS undeliverable addresses rates, CT and OS lost-to-follow-up rates, HT consent for the extended CT and OS HT follow-up, and genetic consent for commercial purposes collection. Having the A&R PMC focus on the activities listed above would allow the Outcomes PMC to focus all its attention on outcomes activities as it has in the past. These activities include monitoring *Form 33D – Medical History Update (Detail)* collection, release of information collection, collection of medical records, assembly of cases for adjudication, and local adjudication.

Since September 2003, the A&R PMC continued its streamlined quarterly review of CCs to better focus of study priorities before closeout: 1) study wide A&R priorities (i.e., stop follow-up, lost-to-follow-up, absolutely no follow-up, undeliverable addresses, E-Alone and CaD study pill collections, and collection rated for *Form 33 – Medical History Update, Form 60 – FFQ, Form 10/17 – HT/CaD Management and Safety*, and *Form 85 – Mammogram*); 2) targeted review and offer of A&R PMC assistance for lower performing CCs; and 3) a cursory review for higher performing CCs. During the discussion of the merger of the two PMC subcommittees, the A&R PMC joined the Outcomes PMC on one committee conference call. One conference call was held with one CC during this time.

Since March 1, the O-PMC held four committee conference calls. A summary of each CC included: 1) recent and cumulative data on collection of required outcomes forms, outcomes packet assembly, and local adjudication; 2) a graph showing the timeliness of outcomes processing over time; 3) CC responsiveness to CCC queries for more information on cancer and CVD cases; and 4) a summary of number of staff and local adjudicators. In the letters to CCs, specific goals were listed for CCs. To facilitate closer monitoring of the outcomes processing at the CCs as close-out nears, the CCC updated the Outcomes Collection and Backlog Report to run monthly. See *Table 8.1*.

During this time, the O-PMC continued its newly established quarterly review of CCs as well. The committee held three targeted conference calls with CCs to discuss issues with outcomes processing in more detail and to provide direction and interim goals for improving performance. CCC outcomes staff also conducted outcomes-focused conference calls with two CCs, holding 7 calls with one CC and 12 with a second CC. The CC outcomes staff also conducted intensive interactions with two CCs, holding 7 conference calls and conducting one three-day visit to one CC and holding 12 calls and conducting two 2-3 day visits with another CC. In the next 6 months, additional targeted calls and possible visits calls with several other CCs are being scheduled.

The PMC report showing data as of February 29, 2004 is in *Tables 8.2 - 8.6*. The CCs also receive these tables quarterly.

Table 8.1

Outcomes Collection and Processing Backlog[1] Data as of 2/29/04

Clinic	Form 33 Missing[2] CT 6/1/03-11/30/03 #	CT %	OS 5/1/02-4/30/03 #	OS %	Form 33D Missing[3] Cumulative #	Cumulative %	Cases[4] Cum #	Cases Ave # / month in last 12 months	Cases # not assigned	Backlog > 2 Months average workload # Cases	Backlog # Months	Backlog # Cases to add/month to catch-up by May 31, 2004	Catch-up Workload # Cases per month	Catch-up Workload # Cases per Day	Catch-up Workload % Increase in ave. workload	Death[5] Cum #	Death[5] % Unresolved	Local Adjudication[6] Cum # Assigned	Local Adjudication[6] # Not Closed
Atlanta	75	4.5	54	2.3	8	0.2	4,559	69	133	0	0	0	69	3	0	184	14.7	4,426	90
Birmingham	94	5.4	189	7.8	10	0.2	6,387	82	158	0	0	0	82	4	0	232	11.6	6,229	61
Bowman	80	7.3	108	7.3	10	0.4	3,297	49	135	37	0.8	12	61	3	24	128	21.1	3,162	8
Winston Salem	31	8.1	32	4.8	1	0.1	1,085	17	19	0	0	0	17	1	0	36	2.8	1,066	6
Brigham	47	2.1	175	6.1	13	0.3	6,044	90	158	0	0	0	90	5	0	162	11.7	5,886	79
Buffalo	40	2.6	66	3.1	13	0.3	5,061	67	121	0	0	0	67	3	0	229	24.5	4,940	32
Chapel Hill	42	2.8	23	1.1	7	0.2	3,729	58	59	0	0	0	58	3	0	136	0.7	3,670	1
Chicago	56	7.3	48	5.0	28	1.5	2,117	32	71	7	0.2	2	34	2	6	79	21.5	2,046	7
Evanston	50	6.4	65	7.2	17	0.9	2,377	32	90	26	0.8	9	41	2	28	84	7.1	2,287	7
Chi-Rush	121	9.6	160	8.2	31	1.1	3,806	52	135	31	0.6	10	62	3	19	162	13.6	3,671	5
Cincinnati	61	4.5	172	6.0	9	0.3	4,257	66	37	0	0	0	66	3	0	140	5.0	4,220	5
Columbus	52	3.5	46	2.1	33	0.9	4,421	61	119	0	0	0	61	3	0	148	14.2	4,302	35
Detroit	195	14.4	211	10.3	25	0.9	3,330	50	155	55	1.1	18	68	3	36	110	16.4	3,175	24
Gainesville	47	4.3	56	4.1	10	0.4	2,980	41	65	0	0	0	41	2	0	122	8.2	2,915	2
Jacksonville	61	6.7	86	6.5	9	0.4	2,582	38	64	0	0	0	38	2	0	95	21.1	2,518	9
GWU-DC	89	6.0	39	1.8	19	0.6	3,957	49	142	44	0.9	15	64	3	31	151	22.5	3,815	33
Honolulu	157	11.5	239	11.6	23	1.1	2,438	39	114	36	0.9	12	51	3	31	122	22.1	2,324	3
Houston	174	14.0	120	5.9	15	0.7	2,369	25	239	189	7.6	63	88	4	252	168	30.7	2,130	187
Iowa City	62	6.3	67	4.7	18	0.7	3,215	50	97	0	0	0	50	3	0	87	17.2	3,118	18
Bettendorf	12	1.7	19	1.6	8	0.4	2,877	38	45	0	0	0	38	2	0	92	6.5	2,832	20
Des Moins	6	0.9	4	1.0	1	0.1	1,431	21	58	16	0.8	5	26	1	24	45	8.9	1,373	36
Irvine	124	7.9	108	5.0	46	1.5	3,123	48	118	22	0.5	7	55	3	15	144	44.4	3,005	19
LA	125	7.7	65	3.1	17	0.5	3,902	53	118	12	0.2	4	57	3	8	155	13.5	3,764	32
LaJolla	235	11.3	311	9.4	148	3.4	4,981	96	592	400	4.2	133	229	11	139	305	23.9	4,389	96
Madison	72	4.7	25	1.3	24	0.8	3,557	49	60	0	0	0	49	2	0	134	17.9	3,497	16
Mediantic	109	7.7	128	6.1	17	0.6	3,653	55	85	0	0	0	55	3	0	175	10.3	3,568	23
Memphis	74	5.5	163	9.0	30	1.0	4,229	62	130	6	0.1	2	64	3	3	168	12.7	4,099	46
MemSal	9	2.9	58	9.8	1	0.1	1,028	19	45	7	0.4	2	21	1	11	65	6.2	983	3
Miami	241	16.7	291	21.5	24	1.1	2,243	33	64	0	0	0	33	2	0	112	31.3	2,179	63
Milwaukee	71	4.5	131	6.0	31	1.0	3,945	56	55	0	0	0	56	3	0	147	10.2	3,890	27
Minneapolis	88	4.6	147	5.5	99	2.2	5,519	72	93	0	0	0	72	4	0	175	17.1	5,426	38
Nevada	33	2.4	29	1.4	20	0.6	4,255	60	114	0	0	0	60	3	0	248	12.1	4,141	25
Newark	131	7.8	265	10.7	27	0.7	4,385	62	193	69	1.1	23	85	4	37	144	25.7	4,192	44
New Brunswick	99	14.6	48	6.0	13	1.0	1,457	21	67	25	1.2	8	29	1	38	64	32.8	1,390	25
NYC	172	9.5	288	10.3	16	0.4	4,697	68	187	51	0.8	17	85	4	25	219	24.7	4,510	48
Oakland	42	2.8	51	2.8	13	0.5	3,064	47	89	0	0	0	47	2	0	178	19.1	2,975	64
Pawtucket	76	4.6	176	8.2	22	0.8	4,726	61	87	0	0	0	61	3	0	172	12.2	4,639	19
Fall River	17	1.9	49	3.7	17	0.8	2,431	41	68	0	0	0	41	2	0	84	34.5	2,365	28
Pittsburgh	107	6.8	125	6.9	2	0.0	6,944	88	187	11	0.1	4	92	5	5	193	8.3	6,757	2
Portland	111	7.1	138	6.4	27	0.9	3,859	60	189	69	1.2	23	83	4	38	172	29.1	3,670	34
San Antonio	126	9.3	177	9.4	12	0.5	2,523	37	52	0	0	0	37	2	0	112	19.6	2,471	29
Seattle	127	7.3	154	9.7	17	0.5	4,229	58	102	0	0	0	58	3	0	193	9.3	4,127	22
Stanford	80	4.7	88	3.4	10	0.3	4,018	63	70	0	0	0	63	3	0	190	14.7	3,948	21
Stony Brook	57	4.4	40	2.0	18	0.6	4,044	64	124	0	0	0	64	3	0	136	13.2	3,920	33
Torrance	151	15.7	155	10.8	12	0.7	2,065	25	56	6	0.2	2	27	1	8	110	23.6	2,009	22
Tucson	101	8.7	86	5.7	0	0.0	4,255	51	93	0	0	0	51	3	0	184	9.8	4,162	11
Phoenix	83	10.2	118	10.4	18	1.0	2,369	35	57	0	0	0	35	2	0	131	18.3	2,312	6
UC Davis	157	8.5	95	4.4	25	0.6	4,995	72	200	56	0.8	19	91	5	26	243	46.9	4,795	79
Worcester	56	3.6	27	1.2	11	0.3	4,327	82	128	4	0.1	1	63	3	2	159	7.5	4,199	56
CC Ave	111	6.7	138	6.1	26	0.7	4,429	64	141	29	0.5	10	73	4	15.4	181	17.9	4,288	40

1 - From CC databases, numbers may not match quarterly CCC reports; 2 - From Task Completeness - Outcomes 33 missing; 3 - From *WHIP2030-Timeliness of Outcomes Processing*; 4 - From *WHIP1263 - Timeliness of Case Packet Assembly* for cum data and last 12 mo data; 5 - From *WHIP1225 -Unresolved Deaths* (unresolved defined as any open death < one year old, or closed but missing proxy *Form 33/33D*. Excludes NDI deaths); 6 - From *WHIP 1264 - Timeliness of Local Outcome Adjudications* for cum data

Table 8.2
Performance Monitoring Committee Report
Data as of 2/29/04
DM

	Adjusted C-I[1]				Task Completeness Form 60 - FFQ[4]		% Stopped[5]	
	Average[2]		Mar 03 - Feb 04[3]		Jun 03 - Nov 03		Cum Feb 04	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Nevada	12.5	1	10.2	1	91.4	2	8.9	2
Oakland	11.4	1	11.6	1	94.8	1	5.9	1
Madison	10.7	1	9.4	1	95.2	1	5.0	1
Iowa City	10.5	1	8.0	2	93.1	1	6.4	1
Columbus	10.5	1	8.5	1	93.3	1	7.8	2
Stanford	10.4	1	8.1	2	89.5	2	7.8	2
Milwaukee	10.4	1	8.7	1	97.1	1	6.5	1
Minneapolis	10.2	1	9.0	1	90.3	2	8.1	2
Pittsburgh	10.1	1	7.6	2	92.8	1	6.5	1
GWU-DC	10.1	1	9.1	1	90.3	2	7.2	1
Seattle	10.1	2	8.1	2	89.9	2	10.6	3
Irvine	9.7	2	9.2	1	83.2	4	8.1	2
Chicago	9.4	2	8.1	2	88.6	2	10.1	3
Portland	9.2	2	8.3	1	87.3	3	10.3	3
Chapel Hill	9.0	2	7.8	2	91.5	2	6.4	1
Worcester	8.9	2	6.7	3	91.6	1	6.3	1
Gainesville	8.9	2	6.5	3	88.8	2	7.2	1
Torrance	8.9	2	7.7	2	74.8	4	13.4	4
UC Davis	8.8	2	6.8	2	82.8	4	11.4	3
Brigham	8.5	2	7.8	2	89.8	2	7.9	2
LA	8.5	3	6.3	3	86.0	3	10.6	3
Tucson	8.4	3	6.7	3	86.5	3	13.0	4
Pawtucket	8.4	3	6.4	3	92.7	1	9.3	2
Buffalo	8.3	3	6.0	3	92.8	1	9.1	2
Chi-Rush	8.2	3	8.7	1	89.4	2	14.5	4
Memphis	8.2	3	6.1	3	82.0	4	12.6	4
Stony Brook	8.2	3	6.3	3	87.2	3	9.0	2
Bowman	8.0	3	5.8	4	87.8	3	12.6	3
Atlanta	8.0	3	7.4	2	85.3	3	7.3	1
Newark	8.0	3	5.8	4	83.2	4	11.3	3
Houston	7.9	4	4.9	4	82.4	4	11.3	3
Cincinnati	7.6	4	5.5	4	94.9	1	9.0	2
Honolulu	7.4	4	4.8	4	84.4	4	17.2	4
NYC	7.4	4	5.7	4	86.6	3	10.4	3
LaJolla	7.3	4	6.0	3	84.4	3	15.2	4
Detroit	7.0	4	6.8	3	85.0	3	14.6	4
Birmingham	6.6	4	5.3	4	81.6	4	11.7	3
San Antonio	5.9	4	4.3	4	86.5	3	14.7	4
MedStar	5.5	4	4.9	4	81.2	4	13.3	4
Miami	4.8	4	5.0	4	74.4	4	22.0	4
CC Average	**8.7**		**7.1**		**87.8**		**10.2**	
Ave F/U 7.1 yr	Design Assumption 11.5				Goal ≥ 90%		Design Assumption 19.3	

[1] Adjusted C-I defined as (C-I of collected FFQs) x (FFQ completion rate)
[2] Based on FFQs collected after randomization through AV9.
[3] Based on FFQs collected in the last 12 months
[4] From *WHIP 1445-Task Completeness*; complete if encounter date on *Form 60* is -6/+12 months from visit target date, using 6 month period
[5] From *WHIP0751- DM Intervention & F/U Status*, includes stopped intervention, stopped F/U, lost-to-F/U, and deaths

Table 8.3
Performance Monitoring Committee Report
Data as of 2/29/04
HT

	E-Alone Adherence Summary ≥ 80%				Task Completeness Jun 03 - Nov 03				% Stopped[5]	
	Average[1]		Mar 03 - Feb 04		Form 10[3]		Form 85[4]		Cum Feb 04	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Oakland	72.4	1	62.0	1	98.1	2	90.9	1	16.2	1
Pittsburgh	63.2	1	50.9	1	96.1	3	90.0	1	28.5	3
Iowa City	63.6	1	51.0	1	96.4	3	91.1	1	18.2	1
Minneapolis	60.3	1	53.5	1	98.3	2	87.8	2	16.9	1
Cincinnati	59.8	1	51.7	1	99.0	1	87.9	2	26.1	2
Stanford	59.2	1	53.7	1	96.0	3	83.4	3	19.4	1
Portland	57.6	1	54.4	1	93.2	3	90.3	1	23.1	2
Nevada	59.1	1	50.3	1	99.1	1	88.0	2	27.9	3
LA	58.0	1	41.0	3	91.7	4	81.5	3	21.7	2
Milwaukee	57.0	1	49.6	1	97.2	2	84.4	3	20.4	1
Brigham	55.9	2	50.2	1	99.2	1	89.0	1	17.6	1
Worcester	55.7	2	46.6	2	98.8	1	94.1	1	20.9	1
Chapel Hill	54.8	2	46.5	2	99.1	1	91.1	1	17.9	1
Pawtucket	53.9	2	42.9	2	98.8	1	92.2	1	27.8	3
Columbus	53.8	2	46.8	2	98.9	1	91.2	1	24.7	2
Honolulu	54.2	2	38.1	3	91.7	4	81.8	3	23.9	2
Gainesville	52.4	2	44.2	2	98.2	2	88.6	2	29.7	3
Chicago	50.2	2	45.5	2	99.3	1	86.9	2	25.0	2
Birmingham	53.0	2	41.5	3	95.8	3	83.0	3	31.3	4
Madison	50.0	2	38.5	3	92.4	4	96.1	1	24.3	2
GWU-DC	49.3	3	40.3	3	86.4	4	79.3	4	16.8	1
Seattle	48.5	3	42.1	2	93.0	3	70.7	4	29.1	3
UC Davis	48.6	3	37.7	3	92.6	4	85.1	3	28.9	3
Bowman	46.5	3	32.7	4	97.8	2	88.9	2	29.4	3
Buffalo	47.0	3	37.5	4	98.6	2	88.0	2	28.7	3
Irvine	46.8	3	38.7	3	97.2	2	73.0	4	26.3	2
Stony Brook	47.5	3	32.8	4	95.5	3	86.0	2	21.1	1
Chi-Rush	46.3	3	44.4	2	96.3	3	79.9	3	31.2	4
Newark	46.1	3	41.5	2	97.9	2	79.9	3	22.3	2
Torrance	44.9	3	39.8	3	92.4	4	72.8	4	27.3	3
LaJolla	43.0	4	29.9	4	89.1	4	68.4	4	30.3	3
NYC	43.6	4	34.8	4	94.6	3	77.0	4	24.4	2
Memphis	43.0	4	42.1	2	99.1	1	80.8	3	34.3	4
Tucson	43.1	4	38.5	3	97.3	2	76.9	4	35.6	4
Atlanta	42.5	4	38.9	3	96.8	3	87.4	2	32.8	4
San Antonio	42.0	4	36.0	4	99.5	1	83.4	3	32.9	4
Detroit	36.4	4	26.0	4	80.7	4	73.4	4	33.0	4
MedStar	33.8	4	32.7	4	98.5	2	86.5	2	32.9	4
Houston	29.8	4	24.1	4	91.4	4	71.9	4	38.5	4
Miami	26.0	4	22.0	4	90.1	4	73.2	4	36.4	4
CC Average	**50.2**		**42.2**		**96.1**		**84.2**		**26.0**	
Ave F/U 6.9 yr	-		-		Goal ≥ 90%		Goal ≥ 90%		Design Assump. 32.3	

[1] Adherence from randomization through 1) 12 months before data as of date 2) last adherence collection within the last 12 months before the data as of date, or 3) death; women off intervention are considered non-adherent

[2] Adherence in previous 12 months; excludes deaths; women off intervention are considered non-adherent

[3] From *WHIP 1445-Task Completeness*,complete if encounter date on *Form 10 - HRT Management and Safety* is -3/+3 months from target date

[4] From *WHIP 1445-Task Completeness*, complete if mammogram date on *Form 85 - Mammogram* date is -12/+6 months from AV target date

[5] From *WHIP CCC750-HRT Intervention & F/U Status*; includes E-Alone stopped intervention (excludes E-plus-P stop intervention), stopped F/U, lost-to-F/U, and deaths as percent of all HT participants

Table 8.4
Performance Monitoring Committee Report
Data as of 2/29/04
CaD

	Adherence Summary ≥ 80%				Task Completeness Form 17[3]		% Stopped[4]	
	Average[1]		Jan 03 - Feb 04		Jun 03 - Nov 03		Cum Feb 04	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Oakland	80.4	1	80.0	1	98.1	2	13.8	1
Stanford	70.7	1	70.3	1	98.3	2	24.5	1
Iowa City	69.9	1	64.3	1	98.0	2	20.3	1
Nevada	67.6	1	68.6	1	99.5	1	23.4	1
Minneapolis	67.4	1	66.4	1	98.4	2	21.7	1
Chapel Hill	64.8	1	67.6	1	99.2	1	14.1	1
Columbus	64.2	1	61.7	2	98.8	1	24.9	2
Gainesville	62.6	1	62.4	1	98.2	2	30.3	3
Portland	61.6	1	62.8	1	96.8	3	27.4	2
Milwaukee	60.9	2	60.9	2	98.9	1	23.0	1
Chi-Rush	61.3	1	60.3	2	96.3	3	31.8	3
Pittsburgh	61.2	2	62.0	2	94.5	4	31.0	3
Brigham	60.5	2	61.0	2	98.9	1	26.0	2
Pawtucket	59.8	2	62.0	2	99.6	1	23.2	1
Cincinnati	59.1	2	63.1	1	99.7	1	29.3	2
Worcester	58.5	2	62.0	2	98.0	2	18.8	1
Madison	57.3	2	57.6	3	97.4	3	24.5	1
Honolulu	56.6	2	55.9	3	96.4	3	34.5	4
Torrance	56.1	3	57.8	3	92.1	4	30.9	3
Birmingham	57.9	2	62.6	1	97.1	3	25.8	2
LA	55.9	3	54.8	3	95.3	4	28.1	2
GWU-DC	56.4	2	54.3	3	95.4	4	28.0	2
Buffalo	56.2	3	61.5	2	99.1	1	22.1	1
UC Davis	55.4	3	59.8	2	96.0	4	30.3	3
Bowman	54.1	3	57.6	3	97.9	3	29.6	3
Seattle	54.6	3	59.5	2	94.2	4	31.6	3
Stony Brook	53.5	3	52.4	3	97.4	3	34.5	4
Atlanta	53.4	3	56.8	3	98.0	2	28.8	2
Tucson	53.2	3	55.6	3	97.8	3	36.3	4
Chicago	52.0	3	54.0	3	98.8	1	33.0	4
San Antonio	51.5	4	52.1	4	99.7	1	31.7	3
LaJolla	49.8	4	45.4	4	96.0	4	31.8	3
Irvine	48.8	4	46.0	4	98.5	2	31.2	3
Newark	48.3	4	49.4	4	92.0	4	30.1	3
NYC	47.9	4	50.7	4	96.4	3	32.0	4
Memphis	47.6	4	50.8	4	97.9	2	40.2	4
Detroit	44.6	4	43.5	4	86.1	4	36.6	4
MedStar	43.5	4	49.6	4	98.1	2	27.3	2
Houston	42.8	4	42.3	4	89.4	4	36.4	4
Miami	32.9	4	38.8	4	97.0	3	47.3	4
CC Average	**57.0**		**57.9**		**97.1**		**28.2**	
Ave F/U 6.0 yr	-		-		Goal ≥ 90%		Design Assump. 28.5	

[1] Adherence from randomization through 1) 12 months before data as of date 2) last adherence collection within the last 12 months before the data as of date, or 3) death; women off intervention are considered non-adherent

[2] Adherence in previous 12 months; excludes deaths; women off intervention are considered non-adherent

[3] From *WHIP 1445-Task Completeness*,complete if encounter date on *Form 17 - CaD Management and Safety* is -3/+3 months from target date

[4] From *WHIP CCC753-CaD Intervention & F/U Status*; includes stopped intervention, stopped F/U, lost-to-F/U, and deaths

Table 8.5
Performance Monitoring Committee Report
Data as of 2/29/04
OS

	% Stopped[1]	
	Cum Feb 04	
	%	Quartile
Brigham	3.8	1
GWU-DC	4.9	1
Chapel Hill	4.8	1
Stony Brook	5.0	1
Worcester	5.1	1
Columbus	5.0	1
Atlanta	5.4	1
Madison	5.8	1
Pawtucket	6.4	1
Iowa City	6.2	1
LA	6.4	1
Minneapolis	6.4	1
Stanford	7.1	2
Newark	7.9	2
Oakland	7.5	2
Portland	7.4	2
MedStar	7.8	2
Bowman	7.8	2
Milwaukee	8.1	2
Buffalo	8.2	3
UC Davis	8.1	2
Gainesville	8.0	2
Chicago	8.7	3
Nevada	8.8	3
Irvine	8.8	3
Birmingham	9.7	3
Cincinnati	8.8	3
Memphis	9.9	3
NYC	9.6	3
Torrance	10.3	4
Detroit	9.9	3
Houston	10.7	4
Seattle	10.0	4
Pittsburgh	11.2	4
Honolulu	11.1	4
San Antonio	10.8	4
Chi-Rush	11.4	4
LaJolla	11.2	4
Tucson	13.2	4
Miami	19.1	4
CC Average	**8.2**	
Ave F/U 6.4 yr	-	

[1] From WHIP CCC752 OS Intervention & F/U Status; includes stopped F/U, lost-to-F/U, and deaths

Table 8.6
Performance Monitoring Committee Report
Data as of 2/29/04
OC

	Task Completeness						Outcomes Processing Mar 03 - Feb 04							
	CT Form 33[1] Jun 03 - Nov 03		OS Form 33[2] Nov 02 - Apr 03		Form 33D[3] Mar 03 - Feb 04		Cases Assembled ≤ 12 weeks[4]		Cases Adjudicated ≤ 14 days[5]		Cases Open > 16 weeks[6]		Cases Clo ≤ 16 weel	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Qua
Chapel Hill	97.2	1	99.0	1	97.2	2	99.1	1	94.2	2	0.0	1	97.8	1
Oakland	97.2	1	96.4	2	97.5	2	81.3	4	62.7	4	31.5	3	67.0	4
Nevada	97.6	1	98.9	1	95.6	3	89.9	2	85.7	3	23.8	2	86.2	2
Brigham	97.9	1	93.5	3	98.5	1	88.1	2	67.7	4	18.5	1	78.9	3
Buffalo	97.4	1	96.1	2	97.0	2	86.8	3	98.6	1	24.8	2	81.9	3
Worcester	96.4	1	98.6	1	98.3	1	92.0	1	81.4	3	17.9	1	87.3	2
Columbus	96.5	1	98.1	1	96.1	3	89.5	2	69.9	4	25.6	2	85.4	2
Iowa City	96.6	1	97.4	1	97.7	2	87.8	2	86.6	3	21.6	2	77.8	3
Madison	95.3	2	99.2	1	95.2	4	92.6	1	61.4	4	27.4	2	88.3	1
Pawtucket	96.4	1	93.7	3	96.6	3	92.2	1	67.1	4	28.9	3	83.8	2
Stony Brook	95.6	1	97.9	1	98.1	2	84.8	3	91.3	2	18.3	1	85.8	2
Stanford	95.3	2	97.1	1	98.5	1	91.3	2	72.8	4	13.7	1	88.9	1
Minneapolis	95.4	2	94.0	3	90.4	4	95.6	1	94.6	2	16.5	1	89.7	1
Milwaukee	95.5	2	92.8	3	95.9	3	92.6	1	96.3	2	12.1	1	90.2	1
Atlanta	95.5	2	97.7	1	99.8	1	91.6	1	84.5	3	30.0	3	86.8	2
Cincinnati	95.5	2	90.4	4	99.3	1	99.2	1	99.9	1	4.5	1	99.3	1
Memphis	95.0	2	93.1	3	96.0	3	87.3	2	97.7	1	29.8	3	82.7	3
Gainesville	94.6	2	95.4	2	98.9	1	91.2	2	99.5	1	18.5	1	90.8	1
Birmingham	94.6	2	92.2	3	98.2	1	82.7	3	96.6	2	45.5	4	76.9	3
GWU-DC	94.0	2	98.6	1	96.8	2	81.5	4	99.6	1	30.3	3	75.6	3
Chicago	93.2	3	93.5	3	96.5	3	84.5	3	98.6	1	39.1	4	77.2	3
Pittsburgh	93.2	3	93.5	3	100.0	1	83.7	3	99.9	1	20.4	2	86.3	2
Irvine	92.1	3	96.0	2	93.9	4	90.4	2	99.6	1	26.9	2	83.1	2
MedStar	92.3	3	96.4	2	97.3	2	81.9	4	93.0	2	33.7	3	83.1	2
LA	92.3	3	96.9	2	96.4	3	73.4	4	91.6	2	45.2	4	66.0	4
Seattle	92.7	3	90.1	4	96.6	2	95.2	1	86.6	3	32.6	3	88.4	1
Bowman	92.5	3	94.2	2	98.8	1	78.6	4	63.5	4	17.1	1	65.5	4
Portland	92.9	3	94.5	2	95.1	4	70.6	4	87.4	3	58.6	4	67.6	4
UC Davis	91.5	3	95.6	2	96.5	3	82.9	3	100.0	1	31.4	3	78.0	3
Tucson	90.7	4	92.0	3	98.0	2	88.2	2	93.8	2	21.1	2	86.4	2
NYC	90.5	4	90.1	4	98.6	1	82.6	3	86.5	3	36.9	4	61.1	4
Newark	90.3	4	91.3	4	95.8	3	85.1	3	38.8	4	37.3	4	72.8	4
San Antonio	90.7	3	90.8	4	96.9	2	91.4	1	79.2	3	28.0	2	90.9	1
LaJolla	88.7	4	90.1	4	84.4	4	69.0	4	76.2	3	67.7	4	45.5	4
Chi-Rush	90.4	4	91.4	4	94.2	4	89.1	2	93.7	2	38.0	4	88.1	1
Honolulu	88.5	4	88.7	4	95.3	4	87.0	3	97.6	1	30.9	3	86.8	2
Houston	86.0	4	94.6	2	92.1	4	50.7	4	52.9	4	47.0	4	27.3	4
Detroit	85.6	4	91.6	3	95.5	3	76.3	4	91.1	3	31.6	3	69.6	4
Miami	83.3	4	78.7	4	94.3	4	86.0	3	54.2	4	26.1	2	64.5	4
Torrance	84.3	4	91.5	4	93.7	4	78.8	4	95.9	2	35.4	4	74.3	3
CC Ave	**93.3**		**94.1**		**96.3**		**86.8**		**85.1**		**32.4**		**80.4**	
Goals	≥ 95.0%		≥ 95.3%		≥ 96.2%		≥ 80%		≥ 80%		< 20%		≥ 80%	

[1] From *WHIP 1445-Task Completeness;* complete if encounter date is -3/+3 months from target date
[2] From *WHIP 1445-Task Completeness;* complete if encounter date is -2/+10 months from AV1,4+ target date, -2/+9 from AV2, and -3/+15 for AV3
[3] From *WHIP 2030-Timeliness of Outcomes Processing;* includes both CT and OS
[4] From *WHIP 1263-Timeliness of Outcomes Packet Assembly;* percent of assembled cases that were assembled (assigned) within 12 weeks
[5] From *WHIP 1264-Timeliness of Local Adjudications;* percent of adjudicated cases that were adjudicated within 14 days
[6] From *WHIP 2030-Timeliness of Outcomes Processing;* percent of open cases that were open more than 16 weeks
[7] From *WHIP 2030-Timeliness of Outcomes Processing;* percent of closed cases that were closed within 16 weeks

9. Other Study Activities

A number of WHI-related scientific endeavors have been initiated by study investigators. Publications in scholarly journals are approved through the Presentations and Publications Advisory Committee and the Project Office. Ancillary studies are approved by the Design and Analysis Advisory Committee and the Project Office. Those initiatives that could potentially threaten the integrity of the Clinical Trial results before the completion of the study are to be referred to the DSMB for review. A full statement of the relevant policies may be found in the *WHI Manuals, Vol. 1 – Study Protocol and Policies, Section 3 – Study Policies.*

Table 9.1 – Publications presents current and proposed publications that have been approved by the Publications and Presentations Committee.

Table 9.2 - Ancillary Studies lists all approved ancillary studies (except for those that have been dropped) along with some key features of the studies and their current funding status.

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
1	Informed Consent in the Women's Health Initiative Clinical Trial and Observational Study	Gen.	**McTiernan**, Rossouw, Manson, Franzi, Taylor, Carleton, Johnson, Nevitt	11	Journal of Women's Health 4(5):519-29, 1995
4	The Women's Health Initiative: Overview of the Nutrition Component	Gen.	**Tinker**, Burrows, Henry, Patterson, Van Horn, Rupp	11	Nutrition and Women's Health, pp. 510-542, 1996.
5	Women Health Initiative: Why Now? What is it? What's New?	Gen.	**Matthews**, Shumaker, Bowen, Langer, Hunt, Kaplan, Klesges, Ritenbaugh	11	American Psychologist. 52(2):101-116, 1997 Feb.
6	Low-fat Diet Practices of Older Women: "Prevalence and Implication for Dietary Assessment"	Gen.	**Patterson**, Kristal, Coates, Ritenbaugh, Van Horn, Caggiula, Snetselaar, Tylavsky	11	Journal of the American Dietetic Association. 96(7):670-9, 1996 Jul.
7	The Evolution of the Women's Health Initiative: Perspectives from the NIH	Gen.	**Rossouw**, Finnegan, Harlan, Pinn, Clifford, McGowan	11	Journal of the American Medical Women's Association. 50(2):50-5, 1995 Mar-Apr
8	Design of the WHI Clinical Trial and Observational Study	Gen.	**Prentice**, Rossouw, Furberg, Johnson, Henderson, Cummings, Manson, Freedman, Oberman, Kuller, Anderson	11	Controlled Clinical Trials 19:61-109, 1998
9	Approaches to Monitoring the Results of Long-term Disease Prevention Trials: Examples from the Women's Health Initiative	CT	**Freedman**, Anderson, Kipnis, Prentice, Wang, Rossouw, Wittes, DeMets	11	Controlled Clinical Trials. 17(6):509-25, 1996 Dec.
11	The Role of Randomized Controlled Trials in Assessing the Benefits and Risks of Long-term Hormone Replacement Therapy: Example of the Women's Health Initiative	CT	**Prentice**, Rossouw, Johnson, Freedman, McTiernan	11	Menopause 3(2):71-76, 1996
12	Factors Associated with Insurance Status among Participants in the WHI	Gen.	**Hsia**, Sofaer, Kiefe, Zapka, Bowen, Mason, Limacher, Pettinger, Lillington	11	Journal of Women's Health & Gender-Based Medicine 9(8):881-889, 2000
13	Depression and Cardiovascular Sequelae in Post-Menopausal Women	Gen.	**Wassertheil-Smoller**, Shumaker, Ockene, Talavera, Greenland, Cochrane, Robbins, Aragaki, Dunbar	11	Arch Intern Med. 2004;164:289-298
16	Caloric Requirements and Dietary Self-report	Gen.	**Hebert**, Patterson, Gorfine, Ebbeling, St. Jeor, Chlebowski	11	Ann Epidemiol 13:1-9, 2003.
17	Sexual Orientation and Health: Comparisons in the Women's Health Initiative Sample	CT	**Valanis**, Bowen, Bassford, Whitlock, Charney, Carter	11	Archives of Family Medicine. 9(9):843-53 , 2000 Sep-Oct
19	Ethnic, Socioeconomic, and Lifestyle Correlates of Obesity in U.S. Women: The Women's Health Initiative	Gen.	**Manson**, Lewis, Kotchen, Allen, Johnson, Stefanick, Foreyt, Klesges, Tinker, Noonan, Perri, Hall	11	Clinical Journal of Women's Health. 1(5):225-34, 2001 Dec

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
21	Hypertension and It's Treatment in Postmenopausal Women: Baseline Data from the Women's Health Initiative	OS	**Wassertheil-Smoller**, Anderson, Psaty, Manson, Wong, Francis, Grimm, Kotchen, Langer, Lasser	11	Hypertension 2000;36:780-89
22	Pelvic Organ Prolapse: Gravity and Gravidity	CT	**Hendrix**, Clark, Nygaard, Aragaki, Barnabei, McTiernan	11	Am J Obstet Gynecol 2002;186:1160-6
24	Estimation of the Correlation between Nutrient Intake Measures Under Restricted Sampling	Gen.	**Wang**, Anderson, Prentice	11	Biometrics. 55, 711-717 (1999)
27	The Effects of Insurance Coverage and Ethnicity on Mammography Utilization in a Postmenopausal Population	Gen.	**Bush**, Langer	11	Western Journal of Medicine 168:236-40, 1998
35	Measurement Characteristics of the WHI Food Frequency Questionnaire	Gen.	**Patterson**, Kristal, Carter, Tinker, Bolton, Agurs-Collins	11	Annals of Epidemiology 1999:9:178-197
37	Depression as Mediated by Social Support, Life Events, and Sexual Activity in Postmenopausal Non-Hispanic White and Latina Women	Gen.	**Larisch**, Talavera, Langer, Velasquez, Elder	11	in press
40	The Health Impact of Domestic Violence in Older Women	OS	**Mouton**, Furniss, Lasser, Rovi	11	Journal of Women's Health & Gender-Based Medicine 1999:8(9):1173-1179
43	Sleep Complaints of Postmenopausal Women	CT	**Kripke**, Freeman, Masaki, Brunner, Jackson, Hendrix, Carter	11	Clinical Journal of Women's Health 1:244-252, 2001
51	The Relationship of Social Support and Social Burden to Breast Cancer Screening in the Women's Health Initiative	Gen.	**Messina**, Lane, Glanz, Smith, Taylor, Frishman, Powell	11	in press, Health Psychology
55	Factor Structure and Factor Invariance of the Women's Health Initiative Insomnia Rating Scale	Gen.	**Levine**, Shumaker, Naughton, Kaplan, Kripke, Bowen	11	Psychological Assesment, 2003, Vol.15, No. 2, 123-136.
59	Risk Factors for Kidney Stones in Postmenopausal Women in the Southern United States	Gen.	**Hall**, Pettinger, Oberman, Watts, Johnson, Paskett, Limacher, Hays	11	Am J Med Sci 2001;322 (1):1-7
60	WHIMS: a Trial of the Effect of Estrogen Therapy in Preventing and Slowing the Progression of Dementia	WHIMS	**Shumaker**, Reboussin, Espeland, Rapp, McBee, Dailey, Bowen, Terrell, Jones	11	Controlled Clinical Trials 19:604-621. 1998
63	Health Insurance as a Determinant of Cancer Screening in WHI OS Participants	OS	**Hsia**, Kemper, Kiefe, Zapka, Sofaer, Pettinger, Bowen, Limacher, Lillington, Mason	11	Preventive Medicine 2000;31:261-270

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
66	Walking compared with vigorous exercise for the prevention of Cardiovascular events in women	OS	**Manson**, Greenland, LaCroix, Stefanick, Mouton, Oberman, Perri, Sheps, Pettinger, Siscovick	11	N Engl J Med, Vol. 347, No. 10. 2002
67	Yogurt Consumption is Associated with Healthy Behavior in Postmenopausal Women	OS	**Mossavar-Rahmani**, Garland, Caan, Hebert, Wodarski, Vitolins, Himes, Parker	11	Clinical Journal of Women's Health 2002:2(3)128-134
69	Correlates of Serum Lypocene in Older Women	CT	**Casso**, White, Patterson, Agurs-Collins, Kooperberg, Haines	11	Nutrition and Cancer 2000:36:163-69.
70	Correlates of Serum Alpha- and Gamma-Tocopherol in the WHI	CT	**White**, Masaki, Chen, Shikany, Caan, Mares-Perlman, Wilson, Kristal	11	Annals of Epidemiology 2001;11:136-144
71	The Women's Health Initiative: Goals, Rationale, and Current Status	Gen.	**Liu**	11	Menopausal Medicine, Vol.6(2), p.1-4, 1998
72	Post-Menopausal Bone Loss and its Relationship to Oral Bone Loss	Gen.	**Jeffcoat**, Lewis, Reddy, Wang, Redford	11	Periodontol 2000, 2000 June;23(1):94-102
76	Labeling as a Predictor of Dietary Maintenance	CT	**Hopkins**, Burrows, Bowen, Tinker	11	J Nutr Educ. 2001; 33:278-283
80	Insulin Resistance and Weight Change in Postmenopausal Black and White Women	Gen.	**Howard**, Adams-Campbell, Pasaro, Black, Stevens, Wagenknecht, Rodrigues, Safford, Allen, Snetselaar	11	In press, Int Journal Obesity
83	A Prospective Study of Physical Activity and the Risk of Breast Cancer in Women Aged 50 - 79 Years	Gen.	**McTiernan**, Kooperberg, White, Wilcox, Coates, Adams-Campbell, Woods, Ockene	11	JAMA. 2003;290:1331-1336.
84	Research Staff Turnover and Participant Adherence in the WHI	CT	**Jackson**, Berman, Snetselaar, Granek, Boe, Huber, Milas, Spivak, Chlebowski	11	Controlled Clinical Trials, 24 (2003) 422-435.
85	The Women's Health Initiative: Rationale, Design and Progress Report	CT	**Johnson**, Anderson, Barad, Stefanick	11	Journal of the British Menopause Society, 1999;5:155-159
86	The Effects of Physical and Emotional Status on Adherence to a Low-fat Dietary Pattern in the Women's Health Initiative	CT	**Tinker**, Perri, Bowen, Patterson, Parker, Wodarski, McIntosh, Sevick	11	JADA June 2002; 102:789-800
88	Estimating Normal Hemogram Values for Postmenopausal Women	Gen.	**Assaf**, Carleton, Miller, Coccio	11	Clinical Journal of Women's Health Vol. 1, No. 1, December 2000, 23-28
91	Compliance with National Cholesterol Education Program Dietary and Lifestyle Guidelines Among Older Women with Self-reported Hypercholesterolemia: The Women's Health Initiative	OS	**Hsia**, Rodabough, Rosal, Cochrane, Howard, Snetselaar, Frishman, Stefanick	11	Am J Med 2002;113;384-92

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
93	Fat Intake in Husbands of Participants in the Dietary Modification Component of the Women's Health Initiative	Gen.	**Shikany**	11	Nutr Res, 2002;22:577-86
95	The Effects of Widowhood on Physical Health, Mental Health, and Health Behaviors; the Women's Health Initiative	OS	**Wilcox**, Evenson, Aragaki, Wassertheil-Smoller, Mouton, Loevinger	11	Health Psychology, 22 (5), 513-522. 2003
98	Antioxidant Use in the Women's Health Initiative Participants	Gen.	**Shikany**, Patterson, Agurs-Collins, Anderson, Wang	11	Preventive Medicine, Vol. 36, Issue 3; Mar 2003, 379-387
99	Risk Factor Clustering in the Insulin Resistance Syndrome and its Relationship to Cardiovascular Disease In White, Black, Hispanic, and Asian Postmenopausal Women	OS	**Howard**, Criqui, Curb, Rodabough, Safford, Santoro, Wilson, Wylie-Rosette	11	Metabolism. 2003 Mar;52(3):362-71.
100	The Yield of Six-Month Recall Mammography on Screening Mammograms	Gen.	**Yasmeen**, Romano, Pettinger, Chlebowski, Robbins, Lane, Hendrix	11	JNCI March 2003; 95(6): 429-436
103	The Women's Health Initiative: Recruitment Complete - Looking Back and Looking Forward (Guest Editorial)	CT	**Rossouw**, Hurd	11	Journal of Women's Health 8:3-5, 1999.
104	Promoting Adherence and Retention to Clinical Trials in Special Populations: A Women's Health Initiative Workshop	Gen.	**Wilcox**, Shumaker, Bowen, Naughton, Rosal, Ludlam, Dugan, Hunt, Stevens	11	Controlled Clinical Trials, 22 (3), 279-289
107	Vigorous Leisure Activity Through Women's Adult Life: The Women's Health Initiative	OS	**Evenson**, Wilcox, Pettinger, Brunner, Daugherty, King, McTiernan	11	Am J Epidemiol 2002;156:-945-953
108	Cross-Sectional Geometry, Bone Strength, and Bone Mass in the Proximal Femur in Black and White Postmenopausal Women	CT	**Nelson**, Barondess, Hendrix, Beck TJ	11	J Bone Miner Res 2000; 15(10):1992-1997
109	Recruitment of women to the WHI: the case of Embajadoras in Arizona	Gen.	**Larkey**, Staten, Ritenbaugh, Hall, Buller, Bassford, Altimari	11	Controlled Clinical Trials: 23(2002); 289-298
112	Results of an Adjunct Dietary Intervention Program in the Women's Health Initiative	OS	**Bowen**, Ehret, Pedersen, Snetselaar, Johnson, Tinker, Hollinger, Lichty, Sivertsen, Ocken, Staats, Beedoe	11	JADA 2002;102:1631-1637
120	Obesity, Body Size, and Risk of Postmenopausal Breast Cancer: The Women's Health Initiative	OS	**Morimoto**, White, McTiernan, Chlebowski, Hays, Stefanick, Margolis, Manson, Kuller, Chen, Muti, Lopez	11	Cancer Causes Control 2002;13:741-751

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
122	Does Statin Use Reduce Risk of Osteoporotic Fracture or Improve Bone Density in Postmenopausal Women? Results from the Women's Health Initiative Observational Study	OS	**LaCroix**, Cauley, Pettinger, Hsia, Bauer, McGowan, Chen, Lewis, McNeeley, Pasaro, Jackson	11	Annals of Internal Medicine 2003; 129:97-104
128	Inflammatory Biomarkers, Hormone Replacement Therapy, and Incident Coronary Heart Disease: A Prospective Analysis from the Women's Health Initiative Observational Study	OS	**Pradhan**, Manson, Rossouw, Siscovick, Mouton, Wallace, Jackson, Pettinger, Ridker	11	JAMA 2002;288:980-987
132	Second Malignancy and Nonmelanoma Skin Cancer: The Women's Health Initiative Observational Study	Gen.	**Rosenberg**, Greenland, Khandekar, Ascensao, Lopez, Sparks	11	Cancer. 2004 Jan 1;100(1):130-8. PMID:14692033
134	Alternative Self-Monitoring Tools in the Dietary Modification Component of the Women's Health Initiative	CT	**Mossavar-Rahmani**, Henry, Rodabough, Bragg, Brewer, Freed, Kinzel, Pederson, Soule, Vosburg	11	J Am Diet Assoc. 2004;104:76-85.
138	Baseline Experience with the Modified Mini-Mental State Exam: The Women's Health Initiative Memory Study	WHIMS	**Rapp**, Espeland, Hogan, Jones, Dugan	11	Aging Ment Health. 2003 May;7(3):217-23.
140	Hysterectomy is an Independent Predictor of Framingham Risk Score	Gen.	**Hsia**, Rossouw, Rodabough, Wassertheil-Smoller, McGovern, Limacher, Oberman, Margolis	11	Am J Cardiol 2003; 92: 264-9
142	Coronary Artery Calcification in Black and White Women	OS	**Khurana**, Rosenbaum, Howard, Adams-Campbell, Detrano, Klouj, Hsia	11	Am Heart J, 2003; 145 : 724-9
145	Breast Cancer and Nonsteroidal Anti-inflammatory Drugs: Prospective Results from the Women's Health Initiative	OS	**Harris**, Chlebowski, Jackson, Frid, Ascensao, Anderson, Loar, Rodabough, White, McTiernan	11	Cancer Research 63, 6096-6101. 2003
155	Changes in Food Sources of Dietary Fat in Response to an Intensive Low-Fat Dietary Intervention: Early Results from the Women's Health Initiative	CT	**Patterson**, Kristal, Rodabough, Caan, Lillington, Mossavar-Rahmani, Simon, Snetselaar, Van Horn	11	JADA, April 2003, Vol 103, Number 4, p. 454-459
166	Is Tea Drinking Related to Bone Mineral Density and Osteoporotic Fractures? ---Results from the Women's Health Initiative Observational Study	OS	**Chen**, Pettinger, Ritenbaugh, LaCroix, Robbins, Caan, Barad, Hakin	11	Am J Epidemiol 2003; 158: 772-781
169	Reliability and Validity of the Women's Health Initiative Insomnia Rating Scale	Gen.	**Levine**, Kaplan, Kripke, Bowen, Naughton, Shumaker	11	Psychological Assesment, 2003, Vol. 15, No. 2, 137-148
171	Prevalence and Correlates of Panic Attacks in Post-Menopausal Women: Results from the Women's Health Initiative	Gen.	**Smoller**, Wassertheil-Smoller, Hendrix, Jackson, Oberman, Sheps	11	Arch Intern Med. 2003;163:2041-2050.

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
177	Validity of Self-Reports of Fractures among Postmenopausal Women in a Prospective Study Results from the Women's Health Initiative	Gen.	**Chen**, Kooperberg, Pettinger, Bassford, Cauley, LaCroix, Lewis, Kipersztok, Borne, Jackson	11	In press, Menopause
179	The Natural History of Pelvic Organ Prolapse in a Cohort of Postmenopausal Women; Data from the UC Davis Site of the Women's Health Initiative	CT	**Handa**, Garret, Hendrix, Gold, Robbins	11	American Journal of Obstetrics and Gynecology . 2004; 190: 27-32
189	Dietary Adherence in the WHI Dietary Modification Trial	CT	**The Writing Group for the WHI Investigators**	11	J Am Diet Assoc. 2004 Apr;104(4):654-658
197	Predictors of Angina vs Myocardial Infarction: Prospective Analysis from the Women's Health Initiative	OS	**Hsia**, Rossouw, Brunner, LaCroix, Wallace	11	Am J Cardiology, 2004. vol 93; No 6: 673-8
198	Aspects of the Management and Coordination of The Women's Health Initiative	Gen.	**Cochrane**, Lund, Anderson, Prentice	11	Diversity in Health Care Research: Strategies for Multisite, Multidisciplinary and Multi-ethnic Projects. J. W. Hawkins, L. A. Haggerty (eds.): pp.181-207 Springer. 2003
203	Estrogen Plus Progestin Influence on Breast Cancer and Mammography in Healthy Postmenopausal Women	CT	**Chlebowski**, Hendrix, Langer, Stefanick, Gass, Lane, Rodabough, Gilligan, Cyr, Thomson, Khandekar, Petrovich, McTiernan	11	JAMA. 2003;289:3243-3253
204	Effect of Estrogen Plus Progestin on Stroke in the Women's Health Initiative	CT	**Wassertheil-Smoller**, Hendrix, Limacher, Heiss, Kooperberg, Rossouw, Kotchen, Curb, Black, Aragaki, Safford, Stein, Laowattana, Mysiw	11	JAMA, 2003 May 28; 289(20):2673-84
208	The Effects of Estrogen Plus Progestin on the Risk of Fracture and Bone Mineral Density: The Women's Health Initiative Clinical Trial	CT	**Cauley**, Robbins, Chen, Cummings, Jackson, LaCroix, LeBoff, Lewis, McGowan, Neuner, Pettinger, Stefanick, Wactawski-Wende, Watts	11	JAMA. 2003;290:1729-1738.
210	Estrogen Plus Progestin and Risk of Coronary Heart Disease: Final Results From the Women's Health Initiative Randomized Clinical Trial	CT	**Manson**, Hsia, Johnson, Rossouw, Assaf, Lasser, Trevisan, Black, Heckbert, Detrano, Strickland, Wong, Crouse, Stein, Cushman	11	NEJM 2003; 349:523-34

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
211	Effects of Estrogen plus Progestin on Health-Related Quality of Life: Results from the Women's Health Initiative Randomized Clinical Trial	CT	**Hays**, Ockene, Brunner, Kotchen, Manson, Patterson, Aragaki, Shumaker, Brzyski, LaCroix, Granek, Valanis	11	NEJM, May 2003;348:1839-1854
221	Gynecologic Cancer Outcomes of the Women's Health Initiative Randomized Trial of Estrogen Plus Progestin	CT	**Anderson**, Judd, Kaunitz, Barad, Beresford, Liu, Pettinger, McNeeley, Lopez	11	JAMA. 2003;290:1739-1748.
224	Estimation of Dependence Between Paired Correlated Failure Times in the Presence of Covariate Measurement Error	OS	**Gorfine**, Hsu, Prentice	11	Journal of Royal Stat Society B. 65: Issue 3, 633-661, August 2003
225	Estrogen Plus Progestin and the Incidence of Dementia and Mild Cognitive Impairment in Postmenopausal Women: The Women's Health Initiative Memory Study (WHIMS)	CT	**Shumaker**, Legault, Rapp, Thal, Wallace, Ockene, Hendrix, Jones, Assaf, Jackson, Kotchen, Wassertheil-Smoller, Wactawski-Wende	11	JAMA.2003;289:2651-2662
226	The Effect of Estrogen With Progestin Treatment on Global Cognitive Function in Postmenopausal Women: Results from the Women's Health Initiative Memory Study	CT	**Rapp**, Espeland, Shumaker, Henderson, Brunner, Manson, Gass, Stefanick, Lane, Hays, Johnson, Coker, Dailey, Bowen	11	JAMA.2003;289:2663-2672
232	Women's Health Initiative: Statistical Aspects and Early Results	Gen.	**Prentice**, Anderson	11	in press, Encyclopedia of Clinical Trials
233	Estrogen Plus Progestin Influence on Colorectal Cancer Risk in Healthy Post-menopausal Women: Results from the Women's Health Initiative (WHI) Randomized Trial	CT	**Chlebowski**, Wactawski-Wende, Ritenbaugh, Hubbell, Ascensao, Rodabough, Rosenberg, Taylor, Harris, Chen, Adams-Campbell, White	11	N Engl J Med 2004; 350. 991-1004
235	Hormone Replacement Therapy and Risk of Cardiovascular Disease	CT	**Kuller**	11	Arterioscler Thromb Vasc Biol. 2003;23: 11-16
240	Risks and benefits of estrogen plus progestin in healthy post-menopausal women: Principal results of the Women's Health Initiative randomized controlled trial.	CT	**The Writing Group for the WHI Investigators**	11	Journal of the American Medical Association 2002;288(3):321-333.
242	Estrogen Deficiency Symptom Management in Breast Cancer Survivors in the Changing Context of Menopausal Hormone Therapy	CT	**Chlebowski**, Kim, Col	11	Semin Oncol. 2003 Dec;30(6):776-88. Review
246	WHI Response to Goodman, Goldzieher and Ayala's Critique of the Women's Health Initiative Report on the Risks and benefits of Estrogen Plus Progestin	CT	**Hendrix**, Prentice	11	Menopausal Medicine. 11:1-4, 2003

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
271	Factors associated with treatment initiation after screening and diagnosis of osteoporosis	CT	**Brennan**, Wactawski-Wende, Crespi, Dmochowski	11	In Press, AJEpi
273	Effects of Conjugated Equine Estrogen in Postmenopausal Women With Hysterectomy. The Women's Health Initiative Randomized Controlled Trial	CT	**The Writing Group for the WHI Investigators**	11	JAMA 2004; 291: 1701-1712
277	Peripheral arterial disease in the randomized E+P trial	CT	**Hsia**, Kotchen, Bonds, Allison, Phillips, Masaki, Langer, Resnick, Caralis	11	Circulation. 109(5):620-626, February 10, 2004
291	Menopausal Hormone Therapy and Breast Cancer: Another view of the WHI Results	CT	**Chlebowski**	11	Editorial, in press
30	Completeness of Purchase Mailing Lists for Identifying Older Women	CT	**Falkner**, Wactawski-Wende, Trevisan	10	
39	Hormone Replacement Therapy and Dietary Fat Intake Influence on Blood Lipids and Insulin in Postmenopausal Women	Gen.	**Chlebowski**, Sparks, Stefanick, Howard, Mossavar-Rahmani, McTiernan	10	
61	WHI Halfway Paper (100K Paper)	Gen.	**Langer**, Kotchen, Daugherty, Lewis, Elmer, Trevisan, Noonan, Hendrix, Adams-Campbell	10	
62	Self-reported Urogential Symptoms in Postmenopausal Women: The Women's Health Initiative	Gen.	**Pastore**, Carter, Hulka, Wells	10	Submitted, Maturitas
113	Prior Use of Oral Contraceptives and Fracture Risk in Menopausal Women	Gen.	**Barad**, Kooperberg, Wactawski-Wende, Hendrix, Watts, Liu	10	submitted, Green Journal
129	Thrombotic Markers for Coronary Heart Disease in Women	OS	**Pradhan**, LaCroix, Trevisan, Lewis, Langer, Hsia, Oberman, Kotchen, Ridker	10	
144	Hysterectomy With and Without Oophorectomy and Risk for Cardiovascular Disease: The Women's Health Initiative	OS	**Howard**, Assaf, Cochrane, Kuller, Lasser, Manson, Stefanick, Trevisan, Van Horn	10	submitted to JAMA 2/04.
164	Leukocyte Count as a Predictor of Cardiovascular Events in Post-Menopausal Women	OS	**Margolis**, Prentice, Greenland, Manson, Assaf, Safford, Howard, Grimm, Bray	10	Submitted to JAMA
186	Physical Activity and Diabetes Risk in Postmenopausal White, Black, Hispanic and Asian Women: The Women's Health Initiative Observational Study	Gen.	**Hsia**, Howard, Limacher, Oberman, Safford, Allen, Torrens, Lawson	10	

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
212	Effect of Estrogen Plus Progestin on Cardiovascular Events and Risk Factors in Postmenopausal Women with Diabetes Mellitus	CT	**Margolis**, Bonds, Rodabough, Tinker, Phillips, Allen, Bassford, Burke, Torrens, Howard	10	submitted, Diabetologia
243	Combined postmenopausal hormone therapy and cardiovascualr disease: toward resolving the discrepency between the clinical trial and observational study at the Women's Health Initiative	CT/OS	**Prentice**, Langer, Stefanick, Howard, Pettinger, Anderson, Barad, Curb, Kotchen, Kuller, Limacher, Wactawski-Wende	10	submitted, JAMA
265	Comparing SF-36 scores of Participants in the Women's Healthy Eating and Living Study, Women's Health Initiative, and Medical Outcomes Study	Gen.	**Yost**, Haan, Levine, Gold	10	submitted to J Clin Epidemiol
274	Association Between Self-Reported Alcohol Intake and Changes in Cognition: Results from the Women's Health Initiative Memory Study (WHIMS)	CT	**Espeland**, Gu, Masaki, Langer, Coker, Stefanick, Ockene, Rapp	10	submitted to Amer J Epidemiology
282	Improving Dietary Self-Monitoring and Adherence with Hand-Held Computers: A Pilot Study	CT	**Glanz**, Murphy, Moylan, Evensen, Curb	10	submitted, American Journal of Preventive Medicine
288	Insulin as Related to Physical Activity and Energy Intake in Postmenopausal Women: Breast Cancer Implications	Gen.	**Chlebowski**, Pettinger, Stefanick, Howard, Mossavar-Rahmani, McTiernan	10	submitted, Cancer, Epidemiology, Biomarkers and Prevention
290	Abnormal Mammograms and Ultra Low Estrogen	CT	**Chlebowski**	10	Editorial, in press
294	Weighted Estimators for Proportional Hazards Regression with Missing Covariates	OS	**Qi**, Wang, Prentice	10	submitted to JASA
25	Hormone Replacement Therapy and the QT Interval	CT	**Kadish**, Greenland, Limacher, Frishman, Daugherty, Parker, Schwartz	9	
26	Special Populations Recruitment for the WHI: Success and Limitations	Gen.	**Fouad**, Corbie-Smith, Curb, Howard, Mouton, Simon, Talavera, Thompson, Wang, White, Young	9	
34	The Relationship between Smoking Status, Body Weight, and Waist-to-Hip Ratio: the WHI	Gen.	**Johnson**, Klesges, Hays, Noonan, Black, Curb, Liu, Manson	9	
41	Determinants of Fasting Hyperinsulinemia	Gen.	**Manson**, LaCroix, Haan, Rodrigues, Wagenknecht, Johnson, Allen, Hendrix	9	

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
73	Innovative Strategies for Monitoring and Enhancing Clinic Performance in the WHI Clinical Trial: The Creation of the Performance Monitoring Committee	Gen.	**Pottern**, Naughton, Lund, Cochrane, Brinson, Kotchen, McTiernan, Shumaker	9	
92	Comparison of Self-report, Discharge Diagnosis, and Adjudication of Cardiovascular Events in the WHI	Gen.	**Heckbert**, Hsia, Kooperberg, McTiernan, Curb, Safford, Psaty, Frishman	9	
102	Cardiovascular Outcomes Related to Anti-Hypertensive Drug Therapy in Older Women: The Women's Health Initiative Observational Study	OS	**Wassertheil-Smoller**, Psaty, Greenland, Margolis, Oberman, Kotchen, Mouton, Hilkert, Black, Anderson, Trevisan, Aragaki	9	
105	Retention of Low Income and Minority Women in Clinical Trials: A Focus Group Study	CT	**Johnson**, Williams, Fouad	9	
111	Effects of Fat Intake on Fat Hedonics: Cognition or Taste?	OS	**Bowen**, Green, Vizenor, Vu, Kreuter, Rolls	9	
126	Influences on Older Women's Adherence to a Low-Fat Diet in the Women's Health Initiative	CT	**Kearney**, Rosal, Ockene, Churchill	9	
147	Association of Hormone Replacement Therapy with Body Fat Distribution in Postmenopausal Women	CT	**Mayo**, Heimburger, Gower, Goran, Fouad, Redden, Oberman, Lewis, McGwin	9	
149	Health Status of Postmenopausal White Women with Back and Leg Pain Living in the Community: A Pilot Study	OS	**Vogt**, Lauerman, Chirumbole, Kuller	9	
163	Racial/Ethnic Differences in Breast Cancer Incidence Rates	OS	**Chlebowski**, Prentice, Patterson, Paskett, Lane, Hubbell, Rohan, Dolan, Anderson, Chen, Aragaki, McTiernan	9	
173	Relationships Between Blood Pressure, Hypertension, and Hypertension Therapy and Measures of Cognition Among WHIMS Women At Baseline	WHIMS	**Johnson**, Espeland, Mouton, Margolis, Masaki, Murphy, Wassertheil-Smoller, Prineas	9	
187	Estrogens and Cardiovascular Disease	OS	**Rossouw**	9	
192	Bone mineral density of American Indian and Alaska Native women: Results from the Women's Health Initiative Study	Gen.	**Whampler**, Howard, Rossouw, Chen	9	

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
200	Repression of Negative Emotion and Ambivalence about Negative Emotion: Associations with Psychosocial and Health-related Outcomes in the Women's Health Initiative	Gen.	**Michael**, Perrin, O'Connor, Wisdom, Ritenbaugh, Bowen, Brzyski, Cochrane	9	
206	Are Postmenopausal Survivors of Breast Cancer at an Increased Risk for Osteoporosis?	Gen.	**Chen**, Barad, Ritenbaugh, Gass, Lopez, LeBoff, Bassford, Maricic	9	
216	Effects of Combination Estrogen-Progestin Hormone Replacement Therapy on Cognition and Affect: The Women's Health Initiative Study of Cognitive Aging	CT	**Resnick**, Maki	9	
220	The Women's Health Initiative: A Glimpse Behind the Scenes	CT	**Furniss**	9	
222	Venous Thromboembolism in the Estrogen plus Progestin Trial of the Women's Health Initiative	CT	**Cushman**, Prentice, Kuller, Sidney, Stafford, Psaty, Rodabough, Rosendaal	9	
229	Symptoms and Side Effects Associated with Combined Estrogen plus Progestin in the Women's Health Initiative	CT	**Barnabei**, Cochrane, O'Sullivan, Schenken, Chen, Johnson, Laube, McGovern, Nygaard, Wells, Williams, Young	9	
326	The Association between osteoporosis and oral bone loss in postmenopausal women	CT	**Wactawski-Wende**, Hovey, Hausmann, Trevisan, Grossi, Genco	9	
38	Relationship of Select Dietary Components and Colorectal Cancer among Postmenopausal Women: The Women's Health Initiative	Gen.	**Frank**, Pettinger, Paskett, Wylie-Rosette, Agurs-Collins	8	
130	Cross-sectional Analysis of Association Between Hormone Replacement Therapy and Thrombotic and Inflammatory Markers for CHD in Women	OS	**Langer**, Manson, LaCroix, Lewis, Hendrix, Rossouw, Pradhan, Ridker	8	
202	Depressive Symptoms and Heart Rate Variability in Postmenopausal Women: An Ancillary Study to the Women's Health Initiative	Gen.	**Sheps**, Kim, McGorray, Bartholomew, Marsh, Dicken, Wassertheil-Smoller, Curb, Oberman, Barton, McMahon	8	
217	Associations with Gun-related Threats and Household Fear in Postmenopausal Women	OS	**Mouton**, Tan, del Aguila	8	
218	The Relationship of Physical and Verbal Abuse with Mental and Emotional Health in Postmenopausal Women	OS	**Mouton**, Rodabough, Cochrane, Brzyski, Rovi, Talamantes, Burge, Katerndahl	8	

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
228	Past Hysterectomy as a Risk Factor for Hypertension in the Women's Health Initiative Observational Study Participants	OS	**Barad**	8	
230	Use of Electric Blankets Increases Risk of Endometrial Cancer	OS	**Abel**, Johnson, Mohanka, Mossavar-Rahmani	8	
248	Progression of Coronary Calcification in Postmenopausal Women	OS	**Hsia**, Klouj, Prasad, Burt, Adams-Campbell, Howard	8	
312	Accuracy of food portion estimation among postmenopausal women	CT	**Coy**, Frank, Lee, Meyskens	8	
332	The Effect of Estrogen on Global Cognitive Function In Postmenopausal Women: Results from the Women's Health Initiative Memory Study	WHIMS	**Espeland**, Rapp, Shumaker, Brunner, Manson, Hsia, Margolis, Wallace, Dailey, Freeman, Hays	8	
336	The Effect of CEE and E+P on Incidence of Dementia and Mild Cognitive Impairment in Postmenopausal Women: Results from WHIMS	WHIMS	**Shumaker**, Legault, Kuller, Rapp, Thal, Lane, Stefanick, Hendrix, Langer, Lewis, Masaki, Coker	8	
29	Effects of Diet Intervention on Motivation to make other Health Related Changes	CT	**Langer**, Lo	7	
53	Dietary, Physical Activity, and Exercise Patterns Among Diabetics	Gen.	**Agurs-Collins**, Dolan, Pasaro, Howard	7	
57	Regional Differences in Stroke Morbidity at Baseline in the WHI	Gen.	**Johnson**, Hall, Oberman, Sheps, Hulka, Hays, Baum, Schenken, Burke, Limacher, Anderson, Jeppson	7	
78	Association Between Antioxidants and BMD in an Ethnically Diverse Population of Older Women	Gen.	**Wolf**, Cauley, Stone, Nevitt, Simon, Jackson, LaCroix, Lewis, Wactawski-Wende, LeBoff	7	
79	Databased Tracking and Statistical Models of the Clinical Trial Recruitment Process	CT	**Creech**	7	
81	The Prevalence of Urinary Incontinence in WHI Women	Gen.	**Hendrix**, Clark, Ling, Dugan, Salmieri, Hurtado, McNeeley, Laube, McTiernan, Francis	7	
188	Electrocardiographic Repolarization Phenotypes and Mortality Risk in Postmenopausal Women	CT	**Rautaharju**, LaCroix, Kooperberg	7	
190	Predictors of LVH	CT	**Oberman**, Ko, Lasser, LaCroix, Wylie	7	

Table 9.1

Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
193	Predictors of Adherence to the Women's Health Initiative Clinical Trial Interventions: A Conceptual Framework	CT	**Rosal**, Shumaker, Snetselaar, Tinker, Cochrane, Bowen, Brunner, Ockene	7	
195	Predictors of Calcium/Vitamin D Supplementation Adherence in the Women's Health Initiative	CT	**Brunner**, Cauley, Snetselaar, Jackson, Cochrane, Granek, Wactawski-Wende	7	
196	Intrapersonal, Interpersonal, Treatment, and Organizational Adherence Predictors in the Women's Health Initiative Dietary Modification Clinical Trial	CT	**Tinker**, Van Horn, Perri, Rosal, Ockene, Patterson, Assaf, Hays, Young	7	
236	Women's Health Initiative Study of Cognitive Aging (WHISCA): Study Design, Implementation, and Data Management	CT	**Coker**, Espeland, Rapp, Resnick, Maki, Hege, Farmer, Shumaker	7	
237	The Women's Health Initiative Study of Cognitive Aging (WHISCA): Rationale, Objectives, and Description of a Randomized Clinical Trial of the Effects of Hormone Therapy on Age-Associated Cognitive Decline	CT	**Resnick**, Maki, Rapp, Espeland, Coker, Shumaker	7	
249	Estrogen Plus Progestin Use and Urinary Incontinence in WHI Women	CT	**Hendrix**, Handa, Aragaki, Barnabei, Cochrane, Iglesia, McNeeley, Naughton, Nygaard, Wallace	7	
272	Estrogen Plus Progestin therapy, medications, and the development of gallstone disease in women in the WHI CT.	CT	**Wallace**, Cirillio, Greenland, LaCroix, Limacher, Rodabough	7	
279	Experiences of women and management of symptoms after stopping estrogen plus progestin in the Women's Health Initiative.	CT	**Ockene**, Cochrane, Barad, Larson, Barnabei, Brzyski, Gass, Gold, Hays, Lane, Manson, Rosal, Wylie-Rosette	7	
285	Estrogen Plus Progestin Influence on Mammogram Density in Healthy Postmenopausal Women in the Women's Health Initiative	CT	**McTiernan**, Martin, Peck, Pisano, Wang, Aragaki	7	
287	Prior menopausal Hormone Therapy and Breast Cancer Risk in the WHI Trial of E+P Therapy	CT	**Anderson**, Chlebowski, Aggerwal, Hubbell, Khandekar, Lane, Lasser, Lopez, Potter, Ritenbaugh, Rossouw	7	
317	Pelvic Organ Prolapse in Older Women: Prevalence and Risk Factors	CT	**Nygaard**, Bradley, Brandt	7	

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
331	Pelvic Floor Symptoms in Older, Community-Dwelling Women	CT	**Bradley**, Kennedy, Nygaard	7	
36	Prevalence of Silent MI	CT	**Sagar**, Kotchen, Wong, Graettinger, Burke, Van Vorhees, McIntosh	6	
87	Incidence and Correlates of Hip and Knee Replacement in the WHI	Gen.	**Wallace**, Chang, Nevitt, LaCroix, Kaplan, Sturm	6	
194	Predictors of Adherence to the Hormone Replacement Therapy Clinical Trial in the Women's Health Initiative	CT	**Cochrane**, Stefanick, Wallace, Granek, Lillington, Anderson, Woods, Naughton	6	
18	The Relationship of Dietary Phytoestrogens to Menopausal Symptoms and Major Morbidity in Postmenopausal Women	CT	**Assaf**, Cyr, Coccio, Hixson	5	
20	Demographic, menstrual, and reproductive correlates of endogenous sex hormone concentrations in the WHI	CT	**McTiernan**, Chen, Rohan, Modugno, Hendrix, Wu	5	
45	Socio-demographic Determinants of Folic Acid Intake	Gen.	**Beresford**, Kritchevsky, Vitolins, Wodarski	5	
54	Current Treatment Patterns in Women with Hypercholesterolemia	Gen.	**Manson**, Freed, Chae	5	
127	Plasma Homocysteine Levels and Coronary Heart Disease in Women	OS	**Siscovick**, Manson, Trevisan, Wallace, Howard, Burke, Ridker	5	
141	The Association of Food and Nutrient Intake with the Incidence of Stroke in the WHI Observational Study	OS	**Beresford**, Shikany, St. Jeor, Torrens, Mossavar-Rahmani, Heiss, Patterson, Van Horn	5	
151	History of Estrogen and Oral Contraceptive Use and Cognitive Function: Results from the Women's Health Initiative Memory Study	WHIMS	**Rapp**, Dailey, Gass, Wactawski-Wende, Hendrix, Hogan, Jones, Murphy, Shumaker	5	
152	The Impact of Magnesium Intake on Bone Mass and Risk of Fracture in the Women's Health Initiative Observational Study	OS	**Jackson**, LaCroix, Lewis, Wactawski-Wende, Cauley, Chen, Bassford	5	
153	Metabolic Syndrome and Depression	CT	**Wylie-Rosette**, Cochrane, Perri, Rapp, Rosal	5	
154	Does Acidogenic Diet Contribute to the Incidence of Hip Fracture?	OS	**Barzel**, Wylie-Rosette, Ritenbaugh, Aickin, LeBoff	5	
156	Incidence of Systemic Lupus Erythematosus in the Women's Health Initiative	OS	**Assaf**, Cyr, Crowley, Coccio	5	

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
159	Endogenous Sex Steroid Hormone and Risk of Coronary Heart Disease in Postmenopausal Women	OS	**Rexrode**, Manson, Kuller, McTiernan, Stefanick, Heckbert, White	5	
160	Correlation of Endogenous Sex Steroid Hormones with Inflammatory and Thrombotic Markers in Postmenopausal Women	OS	**Rexrode**, Manson, Ridker, Cochrane, Ockene, Kotchen, Margolis, McGovern	5	
180	Alcohol Use and the Risk of Endometrial Cancer in the Women's Health Initiative Observational Study	OS	**Assaf**, Beresford, Ockene, Chen, Cyr, Coccio, Moulton, Duffy, Burkholder	5	
181	The Relationship Between Moderate Alcohol Use Folic Acid Intake and Breast Cancer in the Women's Health Initiative Observational Study	OS	**Assaf**, Coccio, Paskett, Lane, Rohan, McTiernan, Duffy, Burkholder	5	
182	The Effect of Moderate Alcohol Consumption on the Incidence of Ovarian Cancer	OS	**Assaf**, Coccio, Anderson, Caan, Kaunitz, DeSantis, Duffy, Burkholder	5	
234	Postmenopausal Hormone Therapy and Body Composition: Results from the Women's Health Initiative E & P Clinical Trial	CT	**Chen**, Bassford, Green, Sylvan, LeBoff, LaCroix, Margolis, Jackson, Cauley, Stefanick	5	
268	The Effects of Estrogen Plus Progestin on the Overall Health of Postmenopausal Women as Measured by a Global Index of Disease Events	CT	**LaCroix**, Anderson, Beresford, Cauley, Chlebowski, Curb, Hendrix, Hubbell, Jackson, Margolis, O'Sullivan, Phillips, Wallace, Aragaki	5	
280	Diet, physical activity, energy balance and endogenous sex hormone concentrations in the WHI	CT	**McTiernan**, Wu, Chlebowski, Modugno, Mossavar-Rahmani, Perri, Stanczyk, Van Horn	5	
284	The Effect of E+P on Bone Mineral Density	CT	**Jackson**, Cauley, Chen, LaCroix, Phillips, Robbins, Rodrigues, Tylavsky, Wactawski-Wende, Pettinger	5	
289	Occurrence of Second Malignancy following Nonmelanoma Skin Cancer: A Prospective OS from the WHI.	OS	**Rosenberg**, Greenland, Khandekar, McTiernan, Rodabough	5	
298	Effect of Aspirin Supplementation on rates of Colorectal Cancer	OS	**Allison**, Langer, Garland, Criqui, Wu	5	
301	Ace-inhibitor Use and Occurrence of Frailty and Disability in Postmenopausal Women	Gen.	**Gray**, LaCroix, Woods, Cochrane, McDermott, Murray, Rodrigues, Black	5	
302	Frailty: Emergence and Consequences in WHI Participants	Gen.	**Woods**, LaCroix, Brunner, Cochrane, Masaki, Murray, Newman	5	

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
303	Statin Use and Occurrence of Frailty and Disability in Postmenopausal Women	Gen.	**LaCroix**, Gray, Woods, Allison, Black, Cochrane, Curb, Greenland, Newman	5	
307	Determinants of retinal levels of lutein and zeaxanthin in older women recruited to participate in the Carotenoids in Age-Related Eye Disease Study (CAREDS)	OS	**Mares-Perlman**, Snodderly, Gruber, Moeller, Ficek, Klein, Wooten, Johnson, Chappel	5	
308	Relationship between Dietary Fat and Age Related Maculopathy in the CAREDS population	OS	**Mehta**, Blodi, Chappel, Moeller	5	
309	Correlates of dietary patterns in older women in the Carotenoids in Age Relatedeye Disease Study (CAREDS)	OS	**Moeller**, Ritenbaugh, Tinker, Moeller, Blodi, Chappel	5	
310	Relationship of Body Fat Level and Distribution to Age Related Maculopathy in the Carotenoids in Age Related Eye Disease Study (CAREDS)	OS	**LaRowe**, Gehrs, Wallace, Chappel	5	
311	Relationship of Supplement Use to Age Related Maculopathy	OS	**Gruber**, Mares-Perlman, Wallace, Moeller, Oxton, Chappel	5	
118	Association Between Depressive Symptomatology and Physical Activity in Post-menopausal Women	Gen.	**Ockene**, Rosal, Haan, Brunner, Mouton, Lopez, Perri, Cochrane, Matthews, Jackson, Sato	4	
124	Relationships Between Nutritional Intake and Measures of Cognition	WHIMS	**Espeland**, Bowen, Haan, Brunner, Snetselaar, Dunn	4	
185	Correlates of Dietary Lutein in Older Women Recruited to Participate in the Carotenoids in Age-Related Eye Disease Study (CAREDS)	OS	**Mares-Perlman**, Allen, Wallace, Ritenbaugh, Tinker	4	
209	Estrogen Metabolism, Body Mass Index, Hormone Replacement Therapy and Post-menopausal Breast Cancer Risk	OS	**Modugno**, Cochrane, Chlebowski, Kuller, Stefanick, Rohan, Lasser, Kip	4	
238	Effects of Timing of Initiation of Menopausal Hormone Therapy and Duration of Prior Use on Cognition and Affect (WHISCA)	CT	**Maki**	4	
250	Treatment with Estrogen + Progestin and age-related maculopathy in the Women's Health Initiative Sight Exam Study (WHISE)	CT	**Haan**, Wallace, Klein, Klein, Hendrix, Seddon, Musch, Hyman	4	

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
251	History of Hormone Replacement Therapy use, Reproductive History and Age-Related Maculopathy in the Women's Health Initiative Sight Exam Study	CT	**Haan**, Wallace, Hendrix, Seddon, Klein, Klein, Musch, Langer, Brunner, Wactawski-Wende	4	
253	Cardiovascular Disease and Age Related Maculopathy in the Women's Health Initiative Sight Exam Study	CT	**Klein**, Klein, Hendrix, Seddon, Langer, Kuller, Brunner, Haan, Hyman, Tomany	4	
256	Inflammation and ARM in the WHISE Study	CT	**Klein**, Klein, Knudtson, Seddon, Wallace, Hyman	4	
259	Alcohol, Caffeine and ARM in the WHISE Study	CT	**Klein**, Seddon, Klein, Johnson, Tomany, Hyman, Musch, Johnson	4	
266	Correlation of endogenous sex steroid hormones with fasting glucose and insulin levels, HOMA indices, and incident diabetes mellitus in postmenopausal women.	OS	**Weinstein**, Rexrode, Ridker, Manson, Kuller, Hankinson, Cochrane	4	
267	Adherence to Dietary Modifcation: A Theoretical Framework	CT	**Rosal**, Ockene, Fletcher	4	
270	The Effect of Calcium plus Vitamin D on Risk for Fractures and Colorectal Cancer: Principal Results of the Women's Health Initiative Calcium plus Vitamin D Trial	CT	**The Writing Group for the WHI Investigators**	4	
275	Association of Prior Hormone Therapy With Cognition During the Women's Health Initiative Memory Study (WHIMS) Estrogen / Progestin Clinical Trial	CT	**Espeland**, Hogan, Dailey, Gass, Hendrix, Murphy, Rapp, Shumaker, Wactawski-Wende	4	
283	Baseline Memory Impairment and HRT as Moderators of the Association between Change in Cognition and Dementia in WHIMS	OS	**Royall**	4	
56	Psychometric Evaluation of the Urinary Incontinence Scale	Gen.	**Levine**, Shumaker, Naughton, Kaplan, Bowen	3	
90	Passive Smoke Exposure in Childhood and Adulthood and Prevalent Coronary Heart Disease in Women Enrolled in the WHI	OS	**Frishman**, Wagenknecht, Wong, Ockene	3	
157	Type 2 Diabetes and Cognitive Functioning in WHIMS	WHIMS	**Haan**	3	

Table 9.1
Publications

Ms ID	Title	Data Focus	Authors	Stage	Reference
161	Reproductive History and Cognitive Function in WHIMS	WHIMS	**Haan**, Frishman, Stefanick	3	
201	Normal Electrocardiographic Patterns in Older Adult Women. Depolarization and Repolarization Phenotypes	Gen.	**Rautaharju**, Prineas, Hsia, Kadish, Lund	3	
207	Comparisons Between Never Smokers, Former Smokers and Current Smokers in the Observational Study of the WHI	OS	**Brunner**, Johnson, Hunt, Paskett, Stevens, Ockene, Bowen	3	
223	Physical Activity and Fracture in the Women's Health Initiative Observational Study	OS	**Wactawski-Wende**, Cauley, Jackson, LeBoff	3	
239	Risks and Benefits of A Low-Fat Dietary Pattern in Healthy Postmenopausal Women: Principal results from the Women's Health Initiative Randomized Controlled Trial	CT	**Patterson**, The Writing Group for the WHI Investigators	3	
245	Factors Associated with Self-Reported Severity of Constipation in the Women's Health Initiative	Gen.	**Morse**, Ockene, Nygaard, Crawford	3	
297	Racial/Ethnic Differences in Menopausal Symptoms in Minority vs. White Women in the Oscohort of WHI at baseline	OS	**Mossavar-Rahmani**, Cochrane, Brzyski, Schenken, Murphy, O'Sullivan, Potter, Kempainen	3	
318	The Association of Depressive Symptoms with BMD and Fracture: A Prospective Study form the WHI OS	OS	**Scholes**	3	

Stage
3=Writing group approved
4=Analysis proposed
5=Analysis in progress
6=Analysis completed
7=Draft manuscript
8=Final ms submitted to P&P & PO
9=Final ms approved
10=Submitted
11=In press/published

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
185	An Assessment of Symptoms and Symptom Self-Management for Women Abruptly stopping Hormone Replacement Study Pills	Cheryl Ritenbaugh	Cheryl Ritenbaugh	none	HRT	155	no	3/04-9/04	funded
184	Measures for Changes in Skeletal Muscle Mass	Zhao Chen	Tamsen Bassford	none	BMD participants	120	no	12/04-12/07	pending
183	Effects of Hormone Therapy (Estrogen Alone or Estrogen Plus Progestin) on Subclinical Neurological Pathology – the MRI Study	Mark Espeland	Marcia Stefanick	14 WHIMS sites	HRT	1450	no	12/03-3/06	pending
181	Estradiol, Cytokines and Bone Turnover: Effects on Hip Fracture	Jane Cauley	Lew Kuller	none	OS	400/400	yes	2004-2008	pending
180	Macrovascular Complications of Diabetes in Postmenopausal Women	Rongling Li	Karen Johnson	none	OS	3164	yes	12/04-11/08	pending
179	Inflammation and Coagulation Pathways in the Etiology of Frailty and Disability in Older Women	Andrea LaCroix	Andrea LaCroix	none	OS	1200/600	yes	1/05-12/07	pending
178	Mammographic Density and Invasive Breast Cancer	Etta Pisano	Gerardo Heiss	none	HRT	317/951	no	2003-2005	funded
177	Relative Risk Differences Between FFQs and Food Records	Amy Subar	Ruth Patterson	all to be invited	DM	600/1200	no	9/03-9/04	funded
175	Physical Function Determinants in Minority Women	J. Skye Nicholas	Tamsen Bassford	none	OS	100/100	no	8/03-8/06	pending
171	Analysis of Heart Rate Variability from Ultra-short Records: The WHI Study	Yvonne L. Michaels	Cheryl Ritenbaugh	none	DM and HRT	76	no	1/03-6/03	funded
169	Risk Factors for Hemorrhagic Stroke Among Postmenopausal Women	Robert Kaplan	S. Wassertheil-Smoller	none	OS	250/250	yes	12/03-11/05	pending

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
167	Sex Hormones, Risk Factors, and Risk of ER+ and ER- Breast Cancer	Steve Cummings	Steve Cummings	none	OS	400/600	yes	6/04-12/05	pending
165	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke	Katherine Hartmann	Gerardo Heiss	none	OS	1500/3200	yes	1/04-2/06	funded
164	The IGF System and Coronary Heart Disease	Robert Kaplan	S. Wassertheil-Smoller	none	OS	350/350	yes	1/04-12/07	pending
163	Hormone Use Following the WHI E+P Trial Termination: A Pilot Study	Jennifer Hays	Jennifer Hays	none	CT & OS	405	no	1/03-12/04	pending
161	Bone Mass Response to Termination of Estrogen + Progestin	Jane Cauley	Lew Kuller	none	CT	350	no	7/02-10/02	funded
160	An Assessment of Symptoms and Symptom Self-Management for Women Abruptly stopping Hormone Replacement Study Pills	Barbara Valanis	Cheryl Ritenbaugh	none	CT	250	no	7/02-8/02	funded
156	The Effect of Domestic Violence on Health Care Costs and Utilization	Charles Mouton	Robert Schenken	none	OS	217/217	no	10/02-9/05	pending
155	Carotenoids, Transforming Growth Factors, and Breast Cancer Risk	Tom Rohan	S. Wassertheil-Smoller	none	OS	3500/3500	yes	4/03-3/06	pending
153	Longitudinal Changes in Hip Geometry and Lower Limb Skeletal Muscle among Aging Women	Zhao Chen	Tamsen Bassford	none	BMD participants	all BMD women	no	7/03-6/08	funded
152	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Gloria Ho	S. Wassertheil-Smoller	none	OS	1700/900	yes	7/03-6/07	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
150	Effect of Airborne Particulate Matter and Other Air Pollutants on the Incidence of Cardiovascular Events in the Women's Health Initiative Observational Study	Joel Kaufman	Garnet Anderson	none	OS	all OS women	no	5/02-4/05	funded
149	Gene-Environment Interactions & Human Breast Cancer Risk	Jennifer Hu	Electra Paskett	none	OS	800/800	yes	1/03-12/04	funded
148	Relationship Between Monoclonal Hemopoiesis and other Molecular Abnormalities and the Development of Leukemia in Older Women	Harvey Preisler	Henry Black	none	OS	59/177	yes	4/03-3/05	pending
146	A Prospective Study of Pancreatic Cancer Pathogenesis	Charles Fuchs	JoAnn Manson	none	OS	106/318	yes	3/03-2/04	funded
141	Periodontal Disease and Subclinical Cardiovascular Disease in Post-Menopausal Women	Joan Dorn	Maurizio Trevisan	none	OS	80	no	4/01-6/01	funded
140	Environmental Epidemiology of Arrhythmogenesis in WHI	Eric Whitsel	Gerardo Heiss	none	CT	all CT women	no	4/03-9/07	funded
139	Follow-up of Healthy Breast Cancer Survivors in the WHI Observational Study	Electra Paskett	Greg Burke	none	OS	416	no	8/01-8/02	funded
137	Platelet Polymorphisms as Risk Factors for Myocardial Infarction in Postmenopausal Women and their Interactions with Hormone Replacement Therapy	Paul Bray	Jennifer Hays	none	OS	1060/2120	yes	10/03-9/07	funded
135	Natural History of Pelvic Organ Prolapse in WHI Women	Ingrid Nygaard	Robert Wallace	none	HRT	400	no	7/01-6/06	funded
134	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Frances-mary Modugno	Lew Kuller	none	OS	200/200	yes	6/02-5/04	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
133	Biochemical and Genetic Markers of Hypertension in White and Black Women	Howard Sesso	JoAnn Manson	none	OS	800/800	yes	12/03-11/07	funded
132	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Simin Liu	JoAnn Manson	none	OS	1800/2700	yes	7/02-6/07	funded
130	A Randomized Controlled Trial of Fat Reduction, Calcium/Vitamin D Supplementation, Hormone Replacement Therapy, and risk of Proliferative Forms of Benign Breast Disease	Thomas Rohan	S. Wassertheil-Smoller	all	DM, HRT	3000	no	7/01-6/06	funded
129	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Howard Strickler	S. Wassertheil-Smoller	none	OS	1700/900	yes	1/02-12/05	funded
128	DNA Mismatch Repair Gene Associated Colorectal, Endometrial and Ovarian Cancer in Postmenopausal Women: a Novel Prospective Population-Based Study	Tom Weber	S. Wassertheil-Smoller	none	OS	1500/1500	yes	7/03-6/07	pending
127	Impact of Risk Perception on Preventive Health Behaviors, Process of Care and Outcomes Among a Diverse Cohort of Women at High Risk of Ischemic Heart Disease	Janice Barnhart	S. Wassertheil-Smoller	none	OS	350	no	4/02-3/06	funded
126	Molecular and Genetic Determinants of Stroke in the Women's Health Initiative Observational Study	Sylvia Smoller	S. Wassertheil-Smoller	none	OS Umbrella Study	1100/1100	yes	7/03-6/06	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
124	Sociocultural Influences on Motivation for and Maintenance of Health-Related Dietary Change Among Women	Joylin Namie	Robert Langer	none	DM	90-150	no	6/00-12/00	funded
122	Feasibility Study of Computerized Tailored Dietary Feedback	Karen Glanz, David Curb	David Curb	none	DM	36	no	3/00-9/00	funded
121	Hyperinsulinemia and Ovarian Cancer	Frances-mary Modugno	Lew Kuller	none	OS	200/200	yes	9/02-8/04	funded
118	Accuracy of Food Portion Estimation Among Postmenopausal Women	Christine L. Coy	Allan Hubbell	none	DM	191	no	12/99-4/00	funded
117	Risk Factors for Dry Eye Syndrome in Postmenopausal Women	Kelley A. Kinney	Rebecca Jackson	none	OS	400	no	2/01-1/04	funded
113	Some Aspects of Mediterranean Diet in Relation to Risk of Chronic Diseases among Postmenopausal Women	Iman Hakim	Tamsen Bassford	none	OS	1000	no	8/99 - 7/02	funded
110	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Kathryn Rexrode	JoAnn Manson	none	OS	385/385	yes	8/00 - 7/03	funded
108	Gene-environment effects and colorectal cancer	Henry Lin	Rowan Chlebowski	none	OS	50/150	yes	1/03-12/03	funded
105	Carotenoids in Age-Related Eye Disease Study	Julie Mares-Perlman	Catherine Allen	21,66,56	OS	2880	yes	5/00 - 4/04	funded
104	Tamoxifen Prevention: Is it acceptable to women at risk?	Joy Melnikow	John Robbins	none	OS	150	no	7/99 - 6/02	funded
103	Effects of Hormone Replacement Therapy on Cognitive Aging: Women's Health Initiative Study of Cognitive Aging (WHISCA)	Sally Shumaker	Sally Shumaker	not specified	HRT	1800	no	4/99 - 3/05	funded
102	Quality of Life Improvements and Willingness to Pay: An Investigation of Selective Estrogen Receptor Modulators	Mona Fouad	Albert Oberman	none	OS	120	no	10/98 - 9/98	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
100	Genetic, Biochemical and Behavioral Determinants of Obesity	Jennifer Hays	Jennifer Hays	58	OS	775	no	through 9/01	funded
99	GENNID Study	Rowan Chlebowski	Rowan Chlebowski	none	ALL	40	no	12/98 - 3/00	funded
98	Bone mineral density as a predictor for periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	none	OS	1000	no	4/02-4/06	funded
97	Modeling serum markers for cost-effective ovarian cancer screening	Garnet Anderson	Garnet Anderson	none	OS	264/528 baseline, 132/264 Yr 3	yes	9/01 - 9/04	funded
95	Work organization, psychological distress, and health among minority older women	Beatriz Rodriguez	David Curb	none	OS	500	no	till 6/01	funded
93	The Epidemiology of Venous Disease	Michael Criqui	Robert Langer	not specified	OS	725	no	3/98 - 6/99	funded
90	Biochemical and Genetic Determinants of fracture in postmenopausal women	Steve Cummings	Steve Cummings	none	OS	400/400	yes	4/03-3/06	funded
86	A Pilot Study to Determine the Sensitivity of Form 39 to Impaired Executive Control Function (ECF) as measured by the CLOX: an Executive Clock-Drawing Task	M.J. Polk	Robert Schenken	none	HRT	50	no	N/A	funded
84	Apolipoprotein E genotype, ERT use, and fat-soluble vitamin intake: Effects on Cognitive Function in Older Women	Julie E. Dunn	Philip Greenland	none	DM+OS	260	no	11/98 - 12/03	funded
83	Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study	Paul Ridker	JoAnn Manson	none	OS	650/650	yes	9/99 - 8/03	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
82	Extension of Bone Mineral Density Assessment in WHI Native American Women	Zhao Chen	Cheryl Ritenbaugh	none	OS	200	no	7/97 - 6/01	funded
78	Community Strategy to Retain Women Enrolled in Research	Mona Fouad	Al Oberman	none	CT	40	no	7/97 - 9/97	funded
76	Tailored Messages to Enhance Adherence of Older Women to Dietary Programs for Breast Cancer control	Rowan Chlebowski	Rowan Chlebowski	none	DM	28	no	9/97 - 8/98	funded
75	Adherence to Dietary Modification in the WHI	Milagros C. Rosal	Judith Ochene	6 (does not specify which CC's)	DM	480	no	9/97 - 8/02	funded
74	The Effectiveness of Individual Versus Group Behavioral Strategies to Increase Participants Adherence	Lois Wodarski	Maurizio Trevisan	none	DM	50	no	7/97 - 9/97	funded
73	Psychosocial and Cultural Determinants of NIDDM in Latinas	Deborah Parra-Medina	Robert Langer	22,67,29	OS	228	no	5/97 - 4/98	funded
72	Ethnicity, Body Composition, Bone Density and Breast Cancer	Zhao Chen	Cheryl Ritenbaugh	none	OS	800	no	9/97 - 8/02	funded
70	The Prevalence & Prognostic Importance of Myocardial Ischemia During Daily Life, & its Relationship to Migraine Status: WHI	David Sheps	Gerardo Heiss	10	OS	3200	no	9/97 - 8/00	funded
68	Coronary artery calcification detected with Ultrafast CT as an indication of CAD in OS participants	Judith Hsia	Judith Hsia	51	OS	782	no	1/97 - 12/05	funded
67	Prevalence and Natural History of Autoimmune Thyroid Disease in Postmenopausal Women	Marjita Zakarija	Mary Jo O'Sullivan	51	OS	1040	no	ongoing	funded
65	Incidence of Benign breast disease in the DM CT - Pilot	Tom Rohan	Anne McTiernan	all	DM	200	no	4/98 - 6/99	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
63	Development and Evaluation of Eating Style Index	Pam Haines	Gerardo Heiss	not specified	OS	800	no	10/96 - 6/99	funded
62	Prevention of Age-Related Maculopathy in the WHI HRT CT: WHI-SE	Mary Haan	John Robbins	30	HRT	3300	no	1/99 - 1/07	funded
61	Longitudinal Assessment of Memory Functioning in the WHI Clinical Trial	Mary Haan	John Robbins	none	HRT	110	no	on-going	funded
60	Fat Intake in Husbands of WHI Dietary Arm Participants	James Shikany	Al Oberman	none	DM Partners		no	12/96	funded
57	Hispanic Women's Advocacy and Retention Strategies	Cheryl Ritenbaugh	Cheryl Ritenbaugh	none	OS	120	no	9/96 - 8/98	funded
56	Behavioral and psychosocial predictors of dietary change in postmenopausal women	Joan Pleuss	Gregory Burke	none	DM	260	no	9/96 - 8/98	funded
50	Nutrition Practice Guidelines for Maintaining Low-Fat Dietary Change in Post Menopausal Women	Beth Burrows	Ross Prentice	none	DM	200	no	10/96 - 9/97	funded
48	Prostate Ca Survey of Spouses of WHI Screened Women	Sylvia Smoller	Sylvia Smoller	none	All	1607	no	2/96 - 6/96	funded
47	Effect of diet intervention on motivation to make other health-related changes	Langer/Lo	Robert Langer	none	DM	150	no	5/96 - 4/97	funded
40	Ethnic and age differences in use of Mammography	S. Wassertheil-Smoller	S. Wassertheil-Smoller	none	All	All	no	N/A	funded
39	The Effects of HRT on the Development and Progression of Dementia (WHIMS)	Sally Shumaker	Sally Shumaker	all except #18	HRT	4800	no	5/96 - 4/05	funded
36	Hormone Replacement Therapy and Changes in Mammographic Density	Gerardo Heiss	Gerardo Heiss	none	HRT	NA	no	1/98 - 12/02	funded
34	Ethnic Differences in Hip Bone Geometry by DXA and QCT	Dorothy Nelson	Susan Hendrix	none	HRT	330	no	12/96 - 12/02	funded

Table 9.2
Ancillary Studies

AS #	Title	Study PI	WHI Investigator	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Specimens?	Proposed Study Dates	Funding Status
33	The Association of HRT with Abdominal and Total Body Fat in Postmenopausal Women	Charlotte Mayo	Al Oberman	none	OS	690	no	7/95 - 3/96	funded
31	Eye Care Use	Robert Kleinstein	Al Oberman	none	OS	300	no	completed	funded
25	Ankle-Arm Blood Pressure Index Measurement	Kamal Masaki	David Curb	none	OS	2700	no	2/96 - 1/98	funded
24	Cross-ethnic Comparisons of Skeletal Health of Postmenopausal Women in San Diego County	Diane Schneider	Robert Langer	none	OS	168	no	1/95 - 1/97	funded
17	Domestic Violence in Older Women	Charles Mouton	Norm Lasser	none	OS	1000	no	10/94 - 10/96	funded
15	The Relationship between Osteopenia and Periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	none	OS	1300	no	9/96 -09/01	funded
14	High Density Lipoprotein Metabolism	Scott Going, Tamsen Bassford	Tom Moon	none	OS	200	no	7/94 - 6/96	funded
13	Prevalence and Correlates of Lumbar Spinal Stenosis	Molly Vogt	Lew Kuller	none	CT	150	no	completed	funded
11	Validation and Exploration of Sleep and Mood Predictors	Daniel Kripke	Robert Langer	none	OS	600	no	8/95 - 7/99	funded
9	An investigation of oral hard tissue status in relation to skeletal bone mineral density measures and osteoporosis	Marjorie Jeffcoat	Al Oberman	none	OS	650	no	6/95 - 5/04	funded
5	Explanations for the Development of Fat Distaste	Pamela Green	Deb Bowen	none	DM	160	no	4/95 - 9/96	funded